

Peer Review File

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REVIEWER A

Comment 1: Is the total follow up data for Kato 48 weeks (page 7) or 48 months (abstract)?

Reply 1: *The total follow up for Kato is 48 weeks.*

Changes in the text: *This was corrected in the text (page 2, line 49).*

Comment 2: I would adjust the conclusion in the abstract to reflect that rigid bracing is superior to no bracing in terms of pain control but there was no difference between the rigid and soft brace. Therefore, utilizing a soft or rigid brace, whatever is better tolerated by the patient, may be the most reasonable approach. I think this important as a soft brace is appealing with theoretically decreased risk of skin breakdown, better tolerated by the patient, and lower cost.

Reply 2: *This is a great point, and our abstract and discussion will reflect the recommended change.*

Changes in the text: *We have modified our text in the abstract and the manuscript as advised (page 3, lines 54-55; page 16-17, lines 351-361; page 18, lines 383-385).*

Comment 3: Also adjust the discussion to reflect #3, and an entire paragraph should be dedicated to this in the discussion. A review of the risks/benefits of deciding a rigid versus soft brace should be provided. As a spine surgeon, I want to know whether I should provide people with a hard or soft brace, and the article should attempt to answer that question.

Reply 3: *Thank you for this excellent comment. We agree that it is important to review the potential harms and benefits of brace type. In assumption that the comment is referring to comment #2. An additional paragraph reflecting the risks of bracing has been added to the discussion.*

Changes in the text: *A new paragraph was added to the discussion (page 16-17, lines 351-361)*

Comment 4: If possible, it would be interesting to note if any of the patients who did not have a brace or those with a soft brace went on to have some catastrophic failure (i.e. progressive deformity requiring surgery). The same could be noted in patients who had a rigid brace and see if there's a difference between the two groups. I think as spine surgeons, we're often recommending a rigid brace for compressive fractures to prevent progression/deformity, and this should be addressed in the article.

Reply 4: *Thank you for this valuable point. This is one of the primary reasons for conducting this study, as we hypothesized one of the theoretical benefit of rigid bracing is preventing progressive kyphosis/ deformity, which would then require surgical stabilization. However, the data from this study did not show this conclusion, though further rigorous studies are definitely required to further validate this. We have looked back through the included studies to evaluate this. In the article by Kato et al, 3 patients with a soft brace were excluded during brace treatment due to undergoing spine surgery, whereas no patients in the rigid brace group required surgery. One patient in each group had severe collapse progression. One patient in the soft brace group was excluded for developing a neurologic deficit. In the paper by Kim et al, several patients were lost*

to follow up in each group but no reasons why were provided. In the study by Pfeifer et al, patients lost to follow up included 3 pts for continued pain (rigid), 2 with brace discomfort (soft), and 3 that underwent kyphoplasty (control).

Changes in the text: New text was added (page 10, lines 224-227; page 16-17, lines 351-361)

Comment 5: Was there any crossover in the studies?

Reply 5: Excellent point - The original design of the study by Pfeifer et al was for crossover at 6 months. The patients in the control group were put into a brace after 6 months. However, they state that only 3 patients in the rigid brace group agreed to discontinue the brace after 6 months. Therefore, we only included the initial 6 months of comparative data in our analysis, as we have described in the initial manuscript (page 10, lines 219-221)

Changes in the text: no change in the text was necessary for this reply.

Comment 6: Did any patients drop out of the study due to pursuing operative management with either kyphoplasty/vertebroplasty or surgery?

Reply 6: This is a good question and was addressed in our reply to comment 4. Please see that reply above.

Changes in the text: New text was added (page 10, lines 224-227)

REVIEWER B

Comment 1: In the analysis it is unclear to me why and when braces are considered to be soft or rigid. It should be made clear why it is important to make a distinction between a rigid or a soft brace, what are the criteria for defining whether a brace is rigid or soft? I think in this respect that, as different types of braces and their assumed working mechanisms cannot be defined, all comparisons between rigid and soft braces are useless for the purpose of this study. The aim should be to look for efficacy versus conservative care (as listed in the aim, lines 73-74, p.3), and thus only include results of studies that randomized between a brace and conservative treatment, not between type A and type B brace. Therefore, the study of Kato et al should be excluded from analysis as it does not answer the research question.

Reply 1: Thank you for this excellent suggestion. We agree that there is not a clear definition between soft and rigid bracing, as there are many types and manufacturers. This is a limitation and will be addressed in the manuscript limitations section. We feel that it is valuable to study the available randomized-controlled data on the subject. Our findings are valuable in that they indicate that there may not be a difference between soft and rigid bracing. Therefore, soft bracing may be a reasonable alternative. This is explained and addressed in response to Reviewer A's comments. We understand your reasoning but given the low number of randomized studies available on the topic and the valuable comparison it provides between bracing types, we will respectfully disagree with removing the study. However, we have now performed a subgroup analysis of both rigid and soft bracing groups from the Kim and Pfeifer studies compared to no

brace. That analysis shows significant pain reduction by 6 months. This figure and the associated results and discussion will be added to the manuscript.

Changes in the text: *New text was added (page 7, lines 155-158). A new figure has been added (Figure 3) as well as associated discussion (page 16-17, lines 357-361).*

Comment 2: Line 201; how many patients in comparison between rigid brace and no brace?

Reply 2: *Thank you - There are 54 patients in the “rigid brace” group and 51 patients in the “no brace” group.*

Changes in the text: *This information is provided in figure 2, as referenced in the sentence you have cited (no further changes to manuscript).*

Comment 3: Line 257: subacute is < 3 months.

Reply 3: *Thank you for pointing out this oversight. We will remove this mistake from the text*

Changes in the text: *Text was deleted to avoid confusion (page 14, line 309).*

Comment 4: Lines 277 and further in Discussion: Looking at the results and literature I do not see a clear difference in outcome between different braces, and again what are the criteria for defining a brace to be soft or rigid, and what’s the definition of a “dynamic brace”, a device that has also shown good results (Meccariello et al). Shouldn’t be the conclusion that “as yet bracing appears to have a positive effect on pain in the first six months after an OVCF”?

Reply 4: *Excellent point, there do not appear to be clear criteria on defining bracing types in the literature. We defined a rigid brace as one that does not allow motion, and a soft brace as one that provides support but allows motion. We agree with the conclusion you suggested, and have framed it as: “Moderate quality evidence demonstrates rigid bracing of vertebral compression fractures may decrease pain up to 6 months post-injury...” The conclusion was addressed in our reply to comment 1, and changes have been made in the manuscript to reflect that soft bracing may be a reasonable alternative.*

Changes in the text: *See reply to comment 1.*

Comment 5: There are serious limitations to this study, as partially acknowledged: first, the limited number of studies, the different (or not so different?) types of braces with totally variable treatment regimen and the main study that supports the end conclusion (Pfeiffer et al) was sponsored by the company that developed the brace! Therefore, after downgrading, the conclusion should be changed into: There is low quality evidence that bracing may be considered in patients with OVCFs up to 6 months after onset etc.

Reply 5: *Thank you for this comment. We agree that these are limitations, and they are described in our original manuscript in the “Discussion” section: “Evidence was downgraded from high to moderate due to risk of bias in the study by Pfeiffer et al, as the research was conducted by the company that created the orthoses. Low risk of bias was found in the studies by Kato et al and Kim et al. A multi-domain assessment of bias was also performed and revealed some concerns in measurement and adherence due to the patients being aware of their treatment in all included studies, as well as an incomplete evaluation of compliance. This led to a high risk of bias for the domain evaluating deviation from intervention. Low risk of bias was found in randomization, outcome data, and selection domains.”*

Our GRADE assessment was downgraded from high to moderate due to the serious risk of bias from the Pfeifer study. As the concern for bias was already taken into consideration, moderate quality evidence is an appropriate assessment.

Changes in the text: *no changes in the text were made.*

Comment 6: Fig 1, p12: please list the reason for exclusion of the 11 excluded full text articles.

Reply 6: *Studies were excluded if they were not randomized-controlled trials, if their analysis included data for burst fractures, and if they did not have at least 3 months of follow up data.*

Changes in the text: *Text was added (page 9, lines 196-198).*

Comment 7: Figs 3, 4 and 5 (p.13) can be omitted as they solely discuss differences between “different” braces, not between bracing and conservative care.

Reply 7: *Thank you for the comment. As per your suggestion, we have added a subgroup analysis of “bracing (any brace) vs conservative care”. However, we would like to maintain the other figures as per our response to Comment 1 and also Reviewer A’s comment which would be helpful for clinicians deciding between a soft vs rigid brace.*

Changes in the text: *No changes were made in response to this comment.*

REVIEWER C

Comment 1: The authors included 2 studies which analyzed improvement with bracing using the Visual Analogue Scores. The mean difference and improvement over time should be clearly stated in the abstract and discussion. A discussion regarding the authors’ finding and the minimal important difference would aid readers in interpreting the significance of these findings.

Reply 1: *We agree that this would provide important information to the manuscript. Kato et al reported a 4.83 reduction in VAS score in the soft bracing group after 12 weeks of bracing and a 4.32-point reduction in the rigid bracing group. They found no significance when comparing rigid and soft bracing VAS scores ($p = 0.95$). By 48 weeks, the soft brace group had a 0.19 lower average pain score compared to rigid bracing, which was not significant ($p = 0.43$). Kim et al reported a 2.98-point decrease in VAS score in the no brace group at 3 months, a 4.27-point decrease in the soft brace group, and a 4.8-point decrease in the rigid brace group. However, the difference between bracing groups in their analysis was not significant. It is interesting that the pain reduction over 3 months in soft and rigid bracing groups was similar between the two studies. A minimum important difference was not assessed in the included studies, however the minimal clinically important difference (MCID) for VAS score has been previously reported as 1.2. Therefore, this implies a clinically significant difference for bracing vs no bracing, but not specifically with regards to the type of brace*

Changes in the text: *Text was added and changed to reflect the comment above (page 11-12, lines 246-255; page 15, lines 332-333). A new reference was added (reference 21, Copay et al)*

Comment 2: Purported complications of bracing such as supposed loss of muscle (muscle atrophy) or pressure ulcers need to be considered. The available EMG, radiological and clinical

evidence in these areas should be covered. Studies in the wider literature should be included for this (including non-randomized papers)

Reply 2: *Thank you for the comment. We addressed potential issues with brace usage in response to Comments 2 and 3 from Reviewer A. Radiological and clinical evidence of bracing have been investigated and included in our analysis, but EMG evidence differences are outside the scope of our study.*

Changes in the text: *A new paragraph was added to the discussion (page 16-17, lines 351-361)*

Comment 3: Reference to other systematic reviews in this area should be made given the authors' conclusion are actually slightly different in analyzing only the highest quality evidence. However, it should be noted the sample size in these trials is reasonably small despite the prevalence of these osteoporotic compression fractures

Reply 3: *Thank you. It is true that this is the first and only study we know of to include only high-quality RCTs, and not lower-quality studies. We will include this information in the manuscript.*

Changes in the text: *We added text to highlight the above point and added reference 34 to the reference list (page 17, lines 363-367).*

Comment 4: At the authors institution what individual patient factors are taken into consideration when bracing patients?

Reply 4: *At our institution, bracing is often recommended and utilized. Often they are recommended to be used on an as-needed basis for pain control. Patient factors taken into consideration include age, lifestyle, body habitus, type and level of the injury, and other injuries or comorbidities.*

Changes in the text: *As the present study was looking only at RCT on this topic, no changes in the text were made in response to this comment.*

Comment 5: Emphasis on the importance of medical management of osteoporosis in addition to bracing therapy should be noted. This is also a potentially confounder given the aggressiveness of endocrinological treatment must be considered.

Reply 5: *Thank you - Medical management is an important aspect of conservative management and this will be added to the manuscript.*

Changes in the text: *Text has been added (page 15, lines 321-322).*

REVIEWER D

Comment 1: Line155 Search results

Please list up the excluded papers (11 studies) should be included as supplementary material.

Reply 1: *Thank you. This was addressed in our reply to comment 6 from Reviewer B, and a list has been provided as an appendix.*

Changes in the text: *Text was added (page 9, lines 196-198).*

Comment 2: Line166

In addition to the risk of bias for GRADE, you should examine the risk of bias of your study using a domain-specific risk of bias assessment tool, etc.

Reply 2: Thank you for this suggestion. We have completed the risk of bias tool provided by Cochrane. Each domain resulted in a “Low” risk of bias, except the for deviations from the intervention domain, which resulted in high bias, as the participants were aware of their treatment, and there was not a report or measurement of noncompliance. These may influence the outcomes measures, but are also difficult to avoid for the treatment studied. Overall, we determined that there are “some concerns” with the risk of bias in each study due to the above reasons.

Changes in the text: Text has been added (page 9, lines 185-186; page 14-15, lines 311-317).

Comment 3: Regarding the GRADE Assessment of Included Studies on Pain Reduction after Rigid Bracing in Table 1, the results of the reviewers' evaluation should be described for each article. It is not clear why the certainty is moderate.

Reply 3: Thank you for bringing this to our attention. It will be included in the manuscript that the Pfeifer study was the reason for downgrading from high to moderate because the company that designed the orthoses also conducted the study.

Changes in the text: Text has been added (page 14, lines 310-311).

Comment 4: Line192-193

Reports of Kato et al. and Kim et al. use the VAS as a pain index, and the reports of Pfeifer et al. use Miltner's 4-point scale.

How did you convert the pain on Miltner's 4-point scale to VAS?

The method should be described in the text.

Reply 4: As VAS and Miltner's pain scale both evaluate pain but use different scales, standardized mean differences were used for statistical analysis. This is a known technique for converting outcomes measured using different instruments as per the Cochrane Handbook. This was described in our original manuscript, and we will make this more clear in the revised text.

Changes in the text: text was added (page 11, lines 233-234).

Comment 5: Line233

The legend in Figure 3 provides a description of opioid use. Please correct.

Reply 5: Thank you for bringing this to our attention .The Figure Legend document will be revised.

Changes in the text: The Figure Legends document was revised. No changes were made in the manuscript text.

Comment 6: Line242

The legend in Figure 5 provides an explanation of the AVBCP measurements. Please correct.

Reply 6: Thank you for bringing this to our attention .The Figure Legend document will be revised.

Changes in the text: The Figure Legends document was revised. No changes were made in the manuscript text.

Comment 7: Line238—241

In the text, the percentage of opioid use after 3 months is described for each brace. Where are the data from? Please add references.

Reply 7: *Thanks for bringing this to our attention. We will add reference citations to the Kim and Kato studies where these numbers were derived into the text.*

Changes in the text: *References have now been cited in the text (page 13, line 293).*

Comment 8: Line275

Could you discuss about the mechanism why wearing a rigid brace after a vertebral compression fracture leads to long-term pain relief? What are the neurological implications of increased spinal fixation?

Reply 8: *Thank you - This mechanism and details about rigid vs soft bracing was added to the text in response to comments 2, 3, and 4 from Reviewer A.*

Changes in the text: *please see our responses to comments 2, 3, and 4 from Reviewer A.*