Reviewer’s report

Title: Permissive weight bearing in trauma patients with fracture of the lower extremities: prospective multicenter comparative cohort study

Version: 2 Date: 23 Aug 2017

Reviewer: Benedikt Braun

Reviewer's report:

Thank you very much for addressing my concerns and letting me review this once again. I agree with almost all of the changes made and have only minor suggestions for the original points 2, 5 and 7.

The relevant comments are marked blue (see attachment!).

1) I might consider calling it permissive full weight-bearing, rather than permissive weight bearing

The main feature of the permissive weight bearing protocol is the gait-line of the patient. The goal of the protocol is to gradually increase the weight bearing with a correct gait-line and not start off with full weight bearing. At the start of rehabilitation, patients don't get the instruction to fully bear weight on the affected leg. We therefore would like to adhere to the term "permissive weight bearing".

Understood, no problem. I think we both mean the same thing, so that is absolutely fine for me. I myself consider permissive full weight-bearing to be weight-bearing as tolerated, but that's all semantics, so you can absolutely leave this unchanged.

2) Slightly unbiased tone: At times it is implied, that 12 weeks of complete non weight-bearing after all intra-articular fractures of the lower extremity is in line with the AO Principles of Fracture management (see page 6 Lines 14-17: "According to the AO-protocol, postoperative management of (peri)- or intra-articular fractures of the lower extremities consists of non-weight bearing for 6-12 weeks followed by partial weight bearing with a 25%"). However this is only partially true. While the AO Principles do recommend this for fractures around the knee, it is not recommended in acetabular fractures, as studies have shown that forces across the hip joint are higher during non-weight bearing. Here they recommend partial weight bearing. Furthermore several studies have already shown, that patient compliance to weight-bearing recommendations either partial- or permissive full weight-bearing is low. This includes research from our own group confirming low compliance rates already shown by several short term measurements from
other research groups. This has led to some clinics adopting more weight-bearing friendly aftercare regimes with equally good results. The fact that these regimes are already established in quite some clinics (including the authors own institution judging from the background section) and are also highly present in the current literature is not represented in the current article. I would rework this part in the background and discussion section in a more balanced way, to not only reflect current recommendations that might, or might not be employed in some hospitals, but also the current research and what is already known on weight-bearing compliance.

I hereby emphasize the aftercare treatment for the acetabular fractures according the AO principles; "Early mobilization should be stressed and patients encouraged to sit up within the first 24-48 hours following surgery. Patients are then allowed toe-touch weight bearing using crutches. Strengthening exercises and gait training are initiated by the physical therapist. However, weight bearing is not increased for 6-8 weeks. Following an extended ilio-femoral approach or a trochanteric osteotomy, active abduction is avoided for 6-8 weeks. During the third month the patient is allowed to progress to full weight bearing, depending on radiographic evidence of healing." Despite the studies who have shown us that forces across the hip joint are higher, the aftercare in acetabular fractures is still partial weight bearing.

When I referred to the AO guidelines I meant the surgery references that are published online and are a little more updated and frequently used in many clinics. Here the original text is as follows: "Weight bearing: The healing process is usually complete by the end of the 3rd month. The patient should remain on crutches during this period and avoid full weight bearing. Partial weight bearing (up to 20Kg) is preferable to complete non-weight bearing, because forces across the hip joint are higher when the leg is held off the floor. Weight bearing can be progressively increased after 6 weeks in those cases in which there are 2 single fragments that are well reduced and fixed, and good bone quality. With osteoporotic bone or comminuted fractures, delay the weight bearing until fracture healing is completed."

That is certainly not just toe touch weight-bearing. In fact the AO text recommends to actually not non weight-bear. But again it is somewhat a problem of semantics and certainly depends on the source of the recommendation, as long as it's clearly stated to what recommendation you refer, which it is, it does not necessarily have to be changed.
I agree with reviewer 1 about the compliance of the patients following aftercare treatments. The compliance in restricted/partial weight bearing is very low. We add the text about the compliance in the background section of our paper: "While instructions on rehabilitation provided to patients may be clear, patients compliance with a non-weight bearing or limited weight bearing regime has been found to be poor [5,6]. A number of studies found that patients had actually exceeded the prescribed amount of partial weight bearing even though their self-reported compliance was high [6]. Thus, despite their willingness to comply, patients often do not adhere to the suggested restrictions on weight bearing and increase their weight bearing as fracture healing progresses." (See page 3, line number 18-24).

This is a valuable passage that I would include in the Discussion section rather than background, as I would consider this a limitation of the study. Besides that I agree.

3) Not randomizing the study: I understand the authors concerns about randomization, as they do not want patients with different treatment philosophies on the same ward to prevent bias. However I fear that not randomizing, but assigning treatment protocols to different centers introduces a lot more bias to the study. Especially since one study center is already used to and convinced of permissive full weight-bearing. This introduces observer bias. I would at least address this issue in a thorough limitations section, as it has not been mentioned anywhere in the manuscript up to now.

Thank you, since you are quite right. We have changed the text into: "One should take into account that not randomizing the study may introduce an observer bias, which may be a study limitation." Unfortunately, this cannot be avoided. (See page 9, line number 16-17). Of course, we will critically report on this issue in our papers concerning this study.

Very well.

4) More specific study information: While the article is very specific on the outcome measures the included fracture entities remain rather vague, i.e. all peri- or intraarticular fractures that would require non weight-bearing. As this can have different meanings to different clinicians and researchers I would highly recommend providing more specific inclusion criteria based on the AO/OTA classification system to truly make it comparable to other research projects. Type of fracture (although not specified) is already part of the collected demographic variables. I would highly recommend specifying which fracture classification is used and then also provide it as a specific inclusion criterion.
We have now reported the inclusion criteria more specifically concerning the fracture type. (See revisions in table 1, inclusion criteria).

Thank you.

5) Follow up: I understand that the authors are concerned that the results might be equal between treatment groups at a 1 year follow up mark. However there is no way of knowing that and I feel that this would also be an important result, as this is a common follow up for some of the fracture entities studied and might even be too short a follow up for some cases; i.e. acetabulum fractures, with arthritis as the most common complication that usually manifests within a 2 year follow up. This should also be discussed.

In line with the review by Haller et al [3], we think that permissive weight bearing will not affect the results if we extend the follow up to 1 year or more. Clinical studies indicate no difference between treatment protocols in range of motion, functional outcome parameters and radiographic outcomes after 1 year, and no difference in complications, or loss of reduction [3]. (See page 4, line number 16-18).

A second reason is a more pragmatic one. One of the conditions of the funding agency is to finish the study in 2 years. Given a patient influx time of 1 year, in which to include 134 patients in this study, a follow up time of more than 6 months is not feasible.

Understood. I would mention this briefly during the discussion segment as a limitation, as also Haller (your reference 3) acknowledges, that the evidence for this is of only moderate quality, so it is a limitation, even though the pragmatic reason you present is both understandable and valid… Furthermore Haller mentions the ineffectiveness for 1 year follow ups only briefly for Ankle fractures! For some of the fractures you plan to include (acetabulum, tibial plateau, tibial plafond) most of the referenced studies by Haller have a minimum of 1-2 years of follow up, so I still suggest this is mentioned as a limitation in your study, as the reference by Haller does not really apply to some of the fracture entities you include.

6) Insole compliance measurement need to be described in more detail: What insole is used? How is the measurement set up (i.e. sampling frequency)? When and how long is the patient measured? This is very important, as compliance is different at different settings.

Thank you, since you are quite right. We adjusted the text into: "Peak load (% body weight) and step duration (in seconds) as measured by the Sensistep [27] insole pressure measurement system. The Sensistep will be used by the patient only during daytime. The measurements with
the Sensistep will continue until the patient has shown 100% weight bearing. The time for the latter to occur, may differ between patients." (See page 7, line number 27-30). Reference [27] describes in detail the technical aspects of the Sensistep insoles to be used in our study, including the set-up, sample frequency, active measurement ranges, sensor specifications, sandals to be used etc..

Thank you. Good reference.

7) Teaching non weight-bearing: It needs to be specified how the non-weight bearing is taught. There are highly significant differences in the way non or partial weight-bearing is taught that also have significant implications for the ensuing compliance. Some more minor issues should be corrected after the manuscript is changed according to the suggestions above.

It's difficult to find out how the non-weight bearing is taught. However, in a study by van der Vusse et al. [4] among 111 trauma surgeons and orthopaedic surgeons in the Netherlands, it was shown that consensus about the weight bearing aftercare for tibial plateau fractures is limited. (See page 3, line number 16-18).

Very true. Is there a specific way of teaching weight-bearing for the study though? If so it should be clearly stated. If not I would write something like: "Non weight-bearing is taught as per the institutional standard, i.e. weight-scale technique."

In all only minor revisions for the original critiques 2, 5 and 7. If they could be addressed the article can go right to publication as far as I'm concerned.

Thank you for addressing my concerns.
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If not, please specify what is required in your comments to the authors.

Yes

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