Author’s response to reviews

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

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Author’s response to reviews:

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Dear Editor and Reviewer,

We once again would like to kindly thank you for the quick process and review of our manuscript. We are pleased that our manuscript will be placed in your journal.
We hope that we satisfactorily rebutted the comments of the reviewers before the paper can be accepted for publication.

Below we will respond point by point on the comments of the reviewers.

Editor Comments:

Revision 2:

Ethics approval and consent to participate:

In the Declarations section, please can you update the 'Ethics approval and consent to participate' section to confirm that you have already obtained ethical approval for this study, and that patient consent to participate will be obtained. It is important that you include the full name of the ethical committee in this section, and also include a reference number if obtained.

We have now updated the 'Ethics approval and consent to participate' section into: The medical ethics committee of Maastricht University Medical Center, Maastricht, the Netherlands approved this study, reference number: METC 16-4-236. Patient’s informed consent to participate will be obtained by all patients. (See page 10, line number 4-6).

Date of trial registration:

In the Abstract, please can you include the date that the study was successfully registered. Further information regarding our formatting requirements can be found on the Journals' Instructions for Authors web page.

The date of registration is now included: The study is registered in the Dutch Trial Register (NTR6077). Date of registration: 01-09-2016. (See page 2, line number 22-23).
Title page:

Please refer to the Journals Instructions for Authors about how to format the Title page. It is essential that this is updated before acceptance of your manuscript. We note that you have uploaded the title page as an additional file. Please can this be transferred to appear as the first page of your manuscript document.

- Please include ALL listed authors, their email addresses and institutional addresses

- Please indicate who is the corresponding author

We included the title page as the first page of our manuscript. (See page 1).

Reviewer: 1

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.

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.

(exemplary link to AO Surgery Reference for a two column fracture: https://www2.aofoundation.org/wps/portal?!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOKN_A0M3D2DDbz9_UUMMDRyDXQ3dw9wMDAwCTYEKlvEocDQnTr8BDuBoQEh_QW5oKA_Baevup/dl5/d5/L2dJQSevUUt3QS80SmlFL1o2XzJPMDBHSVMywS09PVDEwQVNFMUdWRj
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.

Revision 2:

Thank you for your comment. We have changed the text into: ‘Patients compliance with a non-weight bearing or limited weight bearing regime has been found to be poor [5,6]. In this study, an insole pressure measurement system will be used to monitor the compliance of the patients.’ (See page 9, line number 29-31).

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.

Revision 2:

Thank you, since you are quite right. We have changed the text into: ‘To analyze specific complications; e.g. arthritis, the follow up period of 6 months is too short and could be a limitation in this study. To eliminate this limitation, a patient-questionnaire could be send to all patients in this study after 2 years.’ (See page 9, line number 33-35).

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.”

Revision 2:

Thank you for your comment. We have adjusted the text into: 'Non-weight bearing is taught as per the institutional standard, based on the prescribed aftercare treatment. Insole pressure measurement system will be used to monitor the weight bearing and the compliance of the patients (see below).' (See page 6, line number 19-22).