Author’s response to reviews

Title: In-screw polymethylmethacrylate-augmented sacroiliac screw for the treatment of fragility fractures of the pelvis: a prospective, observational study with 1-year follow-up

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Fixation of an in-screw polymethylmethacrylate-augmented sacroiliac screw for fragility fractures of the pelvis: a prospective observational study with 1-year follow-up

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BMC Surgery

Dear Editor, dear Reviewers,

First of all we thank you for the opportunity to revise our manuscript and therefore we thank the reviewers for their recommendations to improve the manuscript.

In the follow you find a point-to-point response to the reviewer´s comments. Changes in the manuscript made are highlighted.

We hope your concerns were addressed adequately and the manuscript is suitable for publication in your esteemed journal.
Point-to-point response

Reviewer 1:
Melody Zhifang Ni: The paper describes an interesting single arm prospective study aimed at examining the safety of in-screw augmented sacroiliac screw fixation for fragility fractures of the pelvis. The author collected data on quality of life, pain scores mobility and implant failure. There are a number of issues that I would suggest the authors to address:

1. One major issue is the lack of clear comparators which makes it difficult to judge the value of the procedure. Comparators are necessary and need to be clearly stated in the Methods section to guide statistical analyses of the endpoints: pain scores (currently before v after), quality of life (currently against national average), mobility (not declared) and implant failure (not declared).

Authors: The authors understand the reviewer’s concerns. A control group was planed for the presented study, but was not possible. One indication for surgical treatment for described fractures was prolonged immobilizing pain despite of analgesics and physical therapy. Thus, there would be a great bias in case of a non-operative treatment control group do to less pain from the beginning and missing indication for surgical treatment. Moreover, a non-cemented control group was avoided due to less observed implant failure by cement augmentation and thereby related reduced need for supportive surgery.

We have added following in the section Indication for in-screw PMMA-augmented sacroiliac screw fixation “…fractures in case of immobilizing pain despite of adequately given analgesics. Once, mobilization was appropriate possible with analgesics and physical therapy within three days treatment was conservative” to clarify the indications for surgical treatment.

Considering this indication, a non-operative treated control group is absent because prolonged pain related to immobilization is ethically not acceptable for elderly patient to the authors view. Due to missing evidence for declared type of fracture the described surgical technique is our preferred procedure and a comparison with other techniques would include different fracture
types. Furthermore, comparison to literature is impaired because in many studies follow up data are missed.

The authors included this problem in the discussion and limitation section and highlighted the changes made. (p. 11)

Currently, the authors are not able to provide an appropriate control group because for the presented fracture type the PMMA augmented sacroiliac screws are the preferred technique, comparable literature reports are scarce and a historical comparison is impaired by the different indication for surgical treatment.

2. There is one in-hospital death - please explain whether this is related to the procedure

Authors: We apologize for the missing description of this case. The patient had a Leriche’s syndrome not related to our procedure. After transferring the patient to our department of vascular surgery bypass surgery was performed and the patient died due to adverse events and infection related to the bypass surgery 17 days after pelvic fracture fixation. We have added some explanation to the manuscript (p. 8 last paragraph in adverse events).

3. The cohort is overwhelmingly female - how would this skew the results (quality of life for instance, the comparator is age matched group but is it gender matched?)

Authors: Quality of life was age and gender matched. We added this fact to the manuscript. (p. Compared to other studies this is the typical percentage distribution for gender in europe in this age group.

4. The procedure results in 2 re-interventions out of 34 patients - how does this compare to the chosen comparator and what does this say about the complexity of the procedure and impact on patients' quality of life.

Author: Thank you for this comment. Sacroiliac screw fixation is an accepted procedure and used worldwide for pelvic fracture fixation. As in our manuscript discussed, we did not find higher complication rates due to the additional use of PMMA. (p. 10, paragraph 2)

For your concern to the impact on quality of life we did not find a difference to other patients in the follow up. (Added on p. 10, paragraph 2)

Hospital stay was found in both cases 4 days longer as in average.
5. Figure 4 showed that after 12 months the pain scores are significantly diffused compared to at discharge. Please discuss implications and possible reasons.

Authors: This is a quite interesting point. For pain evaluation we are not able to directly associate recorded pain to the pelvic ring fracture. Related to an average patient age of 79 years, the used VAS is possibly influenced by comorbidities such as osteoarthritis or degenerative spine changes. Nonetheless, we are not able to support our theory but think the pelvic pain is leading initially and at the moment of discharge appropriate analgesic therapy is provided. After 1-year follow up analgesics were reduced or stopped and at this point co-morbidities might affect the reported pain level. We did not find signs of implant loosening or malunions of the pelvis explaining the pain radiation.

We have added this issue in the discussion section. (p. 10)

Reviewer 2:

Wei Chen: The authors reported 34 elderly patients with pelvic fragility fractures treated with percutaneous fixation using an in-screw PMMA-augmented sacroiliac screw. This is a useful technique and can serve as a reference. However, I have some concerns:

1. Since patients were only followed up for 12-14 months, although the elderly patients included, it is not proper to state as a long-term follow up.

Authors: We thank the reviewer for his comment and changed the term in our manuscript to 1-year follow up. (p. 1, section introduction, p. 9, section discussion)

2. One patient died at the hospital, please describe the reasons, any relation with the operation?

Authors: We apologize for the missing description of this case. The patient had a Leriche´s syndrome not related to our procedure. After transferring the patient to our department of vascular surgery bypass surgery was performed and the patient died due to adverse events and infection related to the bypass surgery 17 days after pelvic fracture fixation. We have added some explanation to the manuscript (p. 8 last paragraph in adverse events).

3. For lateral compression fracture with obvious displacement, do you perform reduction before fixation? No neurological deficit reported in your case series.
Authors: The presented techniques were solely used in cases of absent severe dislocation. In cases of greater sacral fracture dislocation (FFP III or IV fractures) as recommended by Rommens et al., spinopelvic fixation is used. In these cases, closed reduction is tried if possible. In this study, only transalar sacral fractures were reported and though neurological deficits were found and even atypically for this type of fractures.

4. Does antiosteoporotic medication recommended for these elderly patients? I recommend two articles as reference:

Authors: We have added this concern in our manuscript. (p. 5, section “Physical therapy and antiosteoporotic therapy”) Thank you for pointing this out. All patients suffering a fragility fracture receive antiosteoporotic therapy in our hospital. The therapy is started at admission, if there is not therapy so far. If patients already receive therapy at admission, we perform more diagnostics to optimize therapy according to the German guidelines for antiosteoporotic treatment.

DVO Guidelines for the prevention, diagnosis and therapy of osteoporosis in postmenopausal women and men aged 60 and over. 2014.

www.dv-osteologie.org/dvo_leitlinien/osteoporose-leitlinie-2014