



Response to Kholinne et al regarding: “Preserving the radial head in comminuted Mason type III fractures without fixation to the radial shaft: a mid-term clinical and radiographic follow-up study”

In reply:

We would like to thank the authors (Kholinne et al) of the Letter to the Editor regarding Gregori et al: “Preserving the radial head in comminuted Mason type III fractures without fixation to the radial shaft: a mid-term clinical and radiographic follow-up study” for their interest in our work. We welcome their remarks and are very thankful for their contribution to our study. Below we would like to clarify some of the issues raised in the Letter to the Editor.

As was stated at the beginning of the original paper, in the “Materials and Methods” section, we conducted a retrospective case-control study. As we know from literature, loss of follow-up of orthopedic trauma patients is a common problem in clinical studies.^{7,8} We excluded all patients who could not be followed up for at least 1 year. To our knowledge and based on information from literature, there is a lack of guidelines on the follow-up of fractures.⁵ In our experience, improvement of functional outcome due to remodeling and strengthening exercises can last up to 12 months after operations around the elbow. For these reasons, we included only patients who had been followed up for a minimum period of 1 year. The flow diagram demonstrating the study cohort gives an overview of the frequency of biological radial head spacers and open reduction and internal fixation (ORIF) performed in our department. Eleven of 41 patients (26.8%) were not included in the study; the reasons for this are demonstrated in Figure 1. In group S (*comprising patients treated with biological radial head spacers*), we excluded 7 patients from the final analysis, of whom 1 patient returned to his home country and 3 patients were seen between 3.1 and 7.7 months postoperatively with a mean flexion arc of 111.7°. The remaining 2 patients were followed up for less than 3 months and had insufficient data records for the final analysis of the clinical and radiographic outcome. One of

these remaining 3 patients underwent reoperation due to a dislocated K-wire; however, the patient did not return for further controls; therefore, we were not able to analyze the final outcome properly. In group P (*comprising patients treated with ORIF using mini-plates*), we excluded 4 patients, of whom 1 patient returned to her home country, 1 patient was seen 4.7 months after the trauma with a flexion arc of 105°, 1 patient had insufficient data records, and 1 patient sustained another injury that may have affected the outcome.

Kholinne et al proposed removing case number 3 because the follow-up of this patient was less than 1 year (0.9 in Table 1 in the original paper). We understand that this information is confusing; therefore, we would like to clarify this issue. This patient was included because the final check-up was performed 3 days before his 1-year follow-up. We think that the results would not have changed in these remaining 3 days. If we had excluded case number 3, the average Mayo Elbow Performance Index (MEPI) would have declined from 94.8 to 94.5 in the group of patients treated with biological radial head spacers.

We are also not aware of any strict definitions regarding the terms “short-term,” “medium-term,” and “long-term” follow-up. In literature there are studies presenting mid-term results of patients with a minimum follow-up period of 12 months or less than 2 years.^{1,2,4} In our work, we even presented the results of patients with follow-up periods longer than 10 years after the injury, which might be interpreted as long-term by some authors.^{3,6} We chose the term “mid-term” in our title because the mean follow-up of all included patients was 6.8 years (mean follow-up 6.1 years for patients with biological radial head spacers; mean follow-up 8.1 years for patients treated with ORIF; mean follow-up 8.1 years for both revision cases). Furthermore, most of the included patients were followed up for longer than 2 years (86.7%; 26 of 30 patients). Nevertheless, we agree with Kholinne et al that, in most trials, mid-term results are usually presented as follow-up periods of at least 2 years and longer.

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With regard to the remarks concerning the unequal group sizes, we have to mention that it was one reviewer's recommendation, during the peer review process, to compare our cohort treated with biological radial head spacers with patients treated with full fixation of the radial head to the shaft, in the study period, to understand the frequency of such salvage procedures. For this reason, we searched for patients treated with ORIF in our database and found only 12 patients. During the study period, there was no study protocol and surgery was performed based on the surgeon's preference. At our institution, we usually perform our presented salvage procedure (reconstruction of the radial head without fixation to the shaft) more often. The reasons for this are mentioned at the end of the discussion section in the original paper. It was not our intention to compare such imbalanced sample sizes. Therefore, we did not compare both cohorts using statistical comparative tests to demonstrate *P*-values. The only useful data analysis carried out was using descriptive statistics. Moreover, we presented every case included in the tables transparently. In the end, readers can see how often we performed radial head reconstruction with and without fixation to the shaft. Furthermore, one can see how each patient performed after different follow-up periods ranging between 1 and 11 years.

We thank Kholinne et al for pointing out that this retrospective study design did not comprise randomization. We apologize for the mistake in Figure 1. Of course, we did not perform randomization. However, we clearly stated in the beginning of the "Materials and Methods" section that we had performed a retrospective case-control study.

In our original paper, we mentioned several limitations of our study, which, amongst others, are the retrospective study design and the small study cohort. We would like to take the opportunity to amend this with the high loss to follow-up of 27%. Furthermore, as we discussed in our original paper, most of the cases were treated with low profile mini-fragment hand plates. The use of anatomically contoured radial head plates may result in better outcomes than presented in our study. Lastly, we agree with Kholinne et al that, without a doubt, a prospective, randomized controlled study is needed to prove the validity of this head preserving salvage procedure, across a larger population. At the same time, however, we also have to consider that comminuted Mason type III fractures are not very common and prospective randomized studies are likely to take many years. Therefore, we think that a prospective study would require multicenter participation to warrant adequate follow-up rates and balanced cohort sizes.

With our retrospective study, we wanted to analyze the outcome of radial head spacers after a minimum follow-up period of 1 year and to see if it would be worth planning a prospective randomized study. In conclusion, we would like to thank Kholinne et al for their comments, which will benefit many readers. We hope that

our response will also help readers when extrapolating the results.

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