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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"

To the Editor:

We read with great interest the original article of Gregori et al, which appeared in the November 2019 issue of the *Journal of Shoulder and Elbow Surgery* (*JSES*).[2] The authors presented their clinical experience with a radial head salvage procedure in comminuted Mason type III fractures. Specifically, the article suggests that preserving the native radial head as to "leave it as it is" without fixation to the radial shaft is a reliable option. We would like to congratulate the authors on this study, which introduces a "fresh" and new concept with excellent results. However, we believe that a few issues need to be addressed that hopefully will improve the study.

First of all, Gregori et al enrolled a total of 41 patients with Mason type III radial head fractures in the study. However, a considerable number of patients were excluded (7 of 29 patients [24.1% of the treatment group] and 4 of 12 patients [33.3%]) with loss to follow-up accounting for 11 patients (36.7%). We do understand that loss of follow-up may lead to the possibility of selection bias among the patients who were reported because the study group might not represent the general population. However, we are also aware that there is no rule that provides a standardized loss to follow-up without mistrusting the study result.[1] Some have suggested that <5% loss may result in little bias, whereas >20% loss leads to serious threats to validity.[4] Despite that it may sound like a good rule of thumb, but keep in mind that even small proportions of loss to follow-up patients can lead to significant bias, assuming that those lost to follow-up were with worst clinical outcome. Accordingly, we kindly suggest that the authors discuss the patients lost to follow-up (36.7%) properly, which will help the reader when extrapolating the results.

Secondly, the study was designed as a retrospective case-control study. However, we noticed that randomization was applied to allocate patients into 2 arms groups, which contradicts the study design. Because randomization would not be possible in a retrospective study, it would be better to state this in the study limitations. There is one thing that may "level up" a retrospective case-control study: applying a propensity score matching technique. A propensity score matching technique will give you the randomization effect in a retrospective design study.[3]

Thirdly, the inclusion criteria required at least 1-year follow-up. However, in their Table I regarding the patient demographics of the study group (spacer group), case number 3 had a 0.9-year follow-up. We do understand that in clinical research the definition of "mid-term" follow-up is not only highly subjective but also highly dependent on the pathology, treatment, and patient population. We are also not aware of any regulatory document or clinical research manual that provides a standardized definition of "mid-term" as they apply to follow-up in clinical research. Therefore, we would like to suggest that the inclusion criteria should be revisited or case number 3 be excluded. In addition, the *JSES* requires at least a 2-year follow-up for all patients enrolled in clinical treatment studies, as stated in their policies. On that account, we believe that the authors should highly consider exclusion of case number 3.

We also noticed that there was an unbalanced sample size between the 2 compared groups: study group (22 cases) vs. control (8 cases). We do understand that there is something aesthetically pleasing when we compare 2 equal-sized groups. However, a sample size imbalance is not a telltale sign of a poor study. We suggest that this issue should be mentioned in the discussion. Furthermore, we noticed that the statistical analysis was not mentioned in the methodology. Having an unequal sample size may dramatically affect the statistical power and type I error. Therefore, taking this into account, we suggest that the authors mention the statistical analysis properly, which will help the reader when interpreting these results.

In the end, surgeons face 2 important questions as they read an article: is the report believable, and, if so, is it relevant to be applied to my practice? To conclude, in our

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opinion, the results of the study should be carefully extrapolated in a bigger population.

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