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About "MRI-based determination of occlusal splint thickness for temporomandibular joint disk derangement: a randomized controlled clinical trial" by Hegab et al.

To the Editor:

The recent article by Hegab et al., titled "MRI-based determination of occlusal splint thickness for temporomandibular joint disk derangement: A randomized controlled clinical trial," described the use of magnetic resonance imaging (MRI) to assess the vertical thickness of the occlusal splint for the most effective management of temporomandibular joint internal derangement.[1] The authors drew the conclusion that an increase in splint thickness was associated with an increase in anteroposterior condylar movements, anteroposterior disk movements, and vertical condylar movements and, thus, led to improved clinical outcomes.

What the authors actually did is as follows: half the study patients received repeated MRI scans with splints of different thicknesses (2, 3, 4, 5, and 6 mm), and then the authors used the measurements of the images to select the "most accurate" thickness of the splint for *all* of the patients with the same diagnosis, that is, "4-mm thickness for disk displacement with reduction and 6-mm thickness for disk displacement without reduction." After this, the randomized controlled trial (RCT) was started to compare the clinical outcomes between the disk displacement with reduction groups with the 3-mm-thick 4-mm-thick splints and the disk displacement without reduction groups with the 3-mm-thick and 6-mm-thick splints. As a matter of fact, this method of MRI measurement should not be part of an RCT because inclusion of MRI measurements may lead to logically confusing or wrong conclusions. Therefore, we have to question the interpretations and the conclusion presented in this article. The following are some of the criticisms of the study:

1. The study blended 2 separate processes occurring at different time points—the RCT and the selection of the splint thickness based on MRI measurements. The thickness of the splint was not individualized but was predetermined on the basis of the data analysis performed *before* the RCT was initiated; thus, the study of MRI-based measurements should have been separated from the RCT. Furthermore, none of the conclusions of this MRI study should be incorporated into the RCT.
2. The study criteria for selecting splint thickness were arbitrary and lacked support. The authors claimed that they chose the splint thickness that had the greatest change in the position of the condyle and the disk. However, the movement of the condyle and the disk is smooth and continuous, and the wider the mouth opens, the greater is the movement of the condyle and the disk. Therefore, judging the significance of the movement of the condyle and the disk on the basis of the *P* value does not make sense.
3. In some cases of temporomandibular joint internal derangement, the symptoms are mild and self-limiting, and oral splints should be used as an adjunctive treatment,rather than a definitive treatment. Therefore, the study should have included a placebo control group or a treatment group comprising patients receiving a very thin splint.[2]
4. There are some contradictory statements in the article. Figure 2 indicated that 5 patients did "not meet the inclusion criteria" and 25 patients "declined to participate"; however, in paragraph 5, page 2, it is stated that "8 patients did not meet the inclusion criteria, and 22 were unwilling to participate in the study." The data presented in Table I were very confusing and questionable. For example, the "condyle position changes" was "16.2 ± 1.45 mm" when the 2-mm splint was applied, which is obviously impossible. The upper and lower 95% confidence intervals of the mean were also wrongly calculated.
5. We would like to point out another important clinical consideration. The baseline median (range) pain scores were 7.0 (5.0−8.0) in subgroup IA, 7.0 (4.0−9.0) in subgroup IB, 8.0 (6.0−9.0) in subgroup IIB, and 8.0 (5.0−9.0) in subgroup IIA. Such patients generally require thoughtful pain control management rather than splint therapies.[3]

It is our opinion that the only authentic message that can be taken from this RCT is that "4-mm thick

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vertical splint therapy is better than 3-mm-thick vertical splint therapy for the treatment of disk displacement with reduction, and 6-mm-thick vertical splint therapy is better than 3-mm-thick vertical splint therapy for the treatment of disk displacement without reduction," but study findings have not definitively proven that the 4-mm-thick or the 6-mm-thick vertical splint is the best choice or that an increase in splint thickness can lead to improved clinical outcomes.

We hope the authors find our comments helpful and wish them success in their future endeavors.

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In reply to: About "MRI-based determination of occlusal splint thickness for temporomandibular joint disk derangement: a randomized controlled clinical trial"

To the Editor:

Thank you for the opportunity to respond to the Letter to the Editor regarding our recently published article titled, "MRI-based determination of occlusal splint thickness for temporomandibular joint disk derangement: a randomized controlled clinical trial." We thank the authors for their interest in our article. We would like to take the opportunity to respond to the comments and concerns mentioned in the letter.

1. The authors wrote "The thickness of the splint was not individualized but was predetermined on the basis of the data analysis performed *before* the RCT was initiated." Our study aimed to investigate a new strategy for utilizing magnetic resonance imaging (MRI) to determine the best vertical thickness of the occlusal splint for the management of temporomandibular joint internal derangement. Randomization of patients was dependent on the strategy used to choose the splint thickness and not merely on the splint thickness itself, and this was explained in the article. We were not simply examining the impact of 3 mm vs 4 mm and 6 mm in cases of disk displacement with reduction and disk displacement without reduction. The splint thicknesses of 4 and 6 mm were based on the MRI calculation of the greatest changes in the anterior and vertical movements of the condyle and the disk. In this way, the splint thickness that provided the greatest changes in these parameters was chosen. The core protocol of the study was the randomization of patients on the basis of whether or not MRI data were utilized in selection of splint thickness. The use of MRI measurements made this an evidence-based study. The clinical assessments of the different splint thicknesses (3 mm vs 4 mm, and 3 mm vs 6 mm) provided proof of the efficacy of MRI measurements.
2. We disagree with the comment that "the criteria for selecting the splint thickness are arbitrary and lack support." We suggest that the letter authors peruse (for instance) the articles by Kurita et al.,[1] Hasegawa et al.,[2,3] Jolanta et al.,[4] Badel et al.,[5] Laškarin et al.,[6] Yang et al.,[7] Hu et al.,[8,9] and Liu et al.,[10] that support our choice of selection criteria.
3. The letter writers stated that "in some cases of internal derangement, the symptoms are mild and self-limiting, in which case splints should be used as adjunctive treatment and not definitive treatment." They stated that patients receiving placebo or very thin splint should have been included as a control group in the protocol. We stated in our article that the selection of patients was determined by the RDC standards. Besides, what is the thickness of a "very thin splint"? Is it 0.5 mm, or 1.0 mm, or 1.5 mm, or 2.0 mm? We are unaware of any evidence-based studies regarding the effectiveness of a "very thin splint." The suggestion that it is necessary to include a control group receiving placebo or a very thin splint seems to be based largely on opinions expressed in

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