LETTERS TO THE EDITOR

Re: Correction in Hatayama T, Nakada A, Nakamura H, et al. "Regeneration of gingival tissue using in site tissue engineering by means of weakly denatured collagen scaffold"

To the Editor:

We have noticed an error in reporting the statistical significance of a result in our article titled "Regeneration of gingival tissue using in site tissue engineering by means of weakly denatured collagen scaffold" published in *Oral Surgery, Oral Medicine, Oral Pathology, and Oral Radiology*.[1]

In this study, we wanted to evaluate the effect of 2 types of collagen scaffolds, CS-pH3.0 and CS-pH7.4, for gingival regeneration in beagle dogs. Using a linear mixed regression model, we found not only that both scaffolds improved the tissue thickness but also that there was a statistically significant effect of the CS-pH7.4 scaffold in comparison with the CS-pH3.0 scaffold and concluded that the CS-pH7.4 scaffold is better and is promising for gingival tissue regeneration.

Upon reanalysis, we have found an error in the *P* values reported for the comparison between tissue thicknesses in the presence of the 2 scaffolds. Although both scaffolds showed statistically significant increases in the tissue thickness at the 2-week time point in comparison with the control group as currently reported, the reanalysis indicated that the *P* value is not statistically significant when comparing tissue regeneration between the groups treated with the 2 scaffolds. Rather, because the regression coefficient was smaller for CS-pH7.4 than for CS-pH3.0, it can be concluded that CS-pH7.4 is more effective for epithelial and submucosal regeneration compared with CS-pH3.0.

We would like to revise the Results and Conclusions sections of our report as follows:

Results:

- Although treatment with the CS-pH3.0 scaffold showed better results in terms of gingival regeneration compared with the control, CS-pH7.4 had the highest gingival regeneration, even when intereva-luator differences were considered (CS-pH3.0 scaffold vs CS-pH7.4: −931.6 [95% confidence interval −1628.9 to −234.3] vs 1146.5 [95% confidence interval −1792.0 to −500.9]). Furthermore, the estimated regression coefficient was smaller for CS-pH7.4 than for CS-pH3.0, suggesting that CS-pH7.4 is more effective for epithelial and submucosal regeneration compared with CS-pH3.0.

Conclusions:

- This study revealed that the application of CS-pH3.0 or CS-pH7.4 was effective in healing gingival wound defects in beagle dogs. At 2 weeks after treatment, histologic analysis indicated higher total thickness of the epithelium and submucosa in gingival wounds treated with CS-pH3.0 or CS-pH7.4 than that in control wounds, reflecting the high tissue-regeneration capacity of collagen scaffolds. In addition, although the difference was not statistically significant, the regression coefficient values suggest that the CS-pH7.4 scaffold may be more effective than the CS-pH3.0 scaffold in gingival tissue regeneration. Further studies are needed to validate these findings and extrapolate the results to humans.

Although both scaffolds are effective, further studies are required before it can be concluded that CS-pH7.4 is a better scaffold compared with CS-pH3.0 for gingival regeneration.

We sincerely apologize for the error in reporting the *P* value; however, we hope that this correction will avoid any misinterpretation of the data.

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1. Hatayama T, Nakada A, Nakamura H, et al. Regeneration of gingival tissue using in site tissue engineering by means of weakly denatured collagen scaffold. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2017;124:348-354.

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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