

Letter to the Editor

Authors' Response:

We appreciate the opportunity to respond to the letter from Drs. Allen and Murphy. They raise a number of issues regarding our 2008 publication¹ and suggest that the gain in keratinized tissue (KT) of the tissue-engineered bilayered cell therapy (BCT) was incorrectly reported in the text. We herein clarify their misinterpretation. In the section, Surgical Procedure, we state, "... a partial-thickness dissection was used to remove the mucosa and any remaining KT from the facial aspect of the test and control site." And in the Discussion, we again clearly point out, "... all sites began the study with no AG [attached gingiva] or KT, because it was removed at the surgical visit during the preparation of the recipient bed." Therefore, the 2.40 mm increase in KT over baseline for BCT is correct, as all sites started with no KT. In Table 1 we did report baseline KT (before it was removed) because we were interested if sites with initial KT would perform better than sites without KT at baseline, thinking that perhaps the periosteum of those sites might influence healing. As reported in the Discussion, we found no statistical difference with regard to KT or AG between test and control sites that both started with at least some AG at baseline.

We apologize for any confusion regarding terms. The reason that the total KT at 6 months is referred to as "gain" in KT is that all of the KT is removed during the surgical procedure so that the final value is indeed the amount of KT "gained" as a result of the procedures involved. We also reported the change in KT from what was present initially, but since the initial KT was removed during the procedure, it would be inaccurate to refer to this "change" as a "gain" in KT from the procedure. It is an increase over what was there to begin with, but again, the actual "gain" in KT following the procedure is the total amount of KT reported at the end.

With respect to the study by Pini-Prato et al.,² it appears that we erred in citing that Pini-Prato et al.² only obtained a gain of 1.5 mm KT when, in fact, the case series of six patients reflects a change of 1.95 mm for the middle site. The value of 2.0 mm is also incorrect; the last two sites should be averaged first, since they are within the same patient.

Also, although the "gain" in KT for the procedures in our paper is actually reflected by the final value of KT at 6 months, Allen and Murphy's point is well taken that we should be comparing similar measurements so that the "true" measure to compare from the Pini-Prato et al.² study is actually 2.88 mm. The 2.40 mm of KT at the end of our study for the BCT sites is

comparable to the 2.88 mm of KT observed by Pini-Prato et al.² Even if we use the variable for change for comparison, the amount of change at the end of our study for the BCT sites is 1.33 mm compared to 1.95 mm for the study by Pini-Prato et al.² We chose to downplay these comparisons in our paper's discussion because of the problematic nature of drawing parallels between different populations and surgical techniques, especially when a controlled study is weighed against an uncontrolled study.

Allen and Murphy's fourth paragraph centers around the claim that BCT could stimulate soft tissue regeneration similar to that achieved using a free gingival graft (FGG). They then go on to point out how the FGG was superior to BCT. Our paper clearly states that "FGG significantly outperformed BCT in KT and AG gain." Our publication states that the aim was to assess the safety and effectiveness of BCT to enhance keratinized tissue and wound healing around teeth that do not require root coverage; this was achieved. The average amount of KT achieved by BCT was 2.40 mm \pm 1.02 mm ($P < 0.001$). Ninety-six percent of BCT sites (24/25) demonstrated an increase in KT at 6 months. No claim was made of superiority with respect to KT gain of BCT over FGG. Rather, the safety and effectiveness of BCT to generate KT without the need for donor tissue were demonstrated. As is clearly stated in the title of the publication, this is a pilot study, and while the amount of KT achieved and proportion of cases achieving >2 mm KT were less than FGG, adequate soft tissue regeneration was achieved in the majority of patients (96% of BCT-treated patients demonstrated an increase in KT) with better cosmetics and without donor site morbidity, and thus BCT represents a clinically significant and novel approach to treatment. A multi-center study has now been completed and statistical data will be available soon to confirm the full potential of BCT in clinical practice.

Michael K. McGuire, private practice, Houston, TX; E. Todd Scheyer, private practice, Houston, TX; Martha E. Nunn, Goldman School of Dental Medicine, Boston University, Boston, MA; and Philip T. Lavin, Boston Biostatistics Research Foundation, Framingham, MA.

REFERENCES

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