any clinician who treats Class II malocclusion with removable functional appliances. We thought the results of this research would be a "clinician's delight" and herald a paradigm shift in functional appliance wear time. However, upon thorough perusal of the manuscript, we sensed some concerns along with queries that needed addressing.

The authors claimed that this was the first study to demonstrate no significant differences in skeletal and dental parameters in patients treated with functional appliances prescribed for either PT or FT wear. However, we found this statement to be erroneous because the mean wear time in the FT group was only 12.38 ± 5.89 hours, which does not qualify to be designated as FT wear. The outcomes might have differed had the subjects complied with the prescribed wear regimen.

Incremental advancement,[1] FT wear,[2] and optimum skeletal age for treatment[3] have been considered the 3 pillars for successful functional appliance therapy for maximum skeletal change. Mills and McCulloch[4] reported that the average change was 4.2 mm greater in the Twin-block group compared with untreated controls. However, the investigators relied only on ANB angle for monitoring the skeletal response. Although the linear mandibular length (Ar-Gn) was recorded at baseline, posttreatment change was not reported.

The dichotomy of FT vs PT wear has been a much-debated topic. Dr Clark[2] claimed that only FT wear could induce the necessary pterygoid response. Although there are no differences between the 2 groups, the study does not offer any biological explanation for the same. Had the subjects used the appliance for 22 hours, the changes might have been different.

We would like to raise the following queries to the authors:

1. What made them consider a 2-mm overjet reduction to be clinically significant in Class II, Division 1 malocclusion? With a pretreatment overjet of more than 10 mm, a 2-mm reduction is highly inappropriate.
2. Although it is rightly mentioned that the external validity could be doubtful owing to a hospital-based sample, we believed that it could still be diluted because of "contamination between intervention groups." This is because all subjects were of the same peer group, receiving different instructions for the same appliance. There is no evidence in the article regarding any precautions against a contamination bias.[5]
3. Why was the posttreatment linear skeletal change using Ar-Gn not considered to be important?

This good work should initiate a series of further multicentric research clinical trials based on a strict FT wear regimen, which can quantify the skeletal and dental response accurately before accepting the PT hypothesis. However, to a compliant patient who is ready to wear the appliance according to the doctor's instructions, it would be inappropriate to tell him or her that PT wear of the appliance is "OK" in light of this research. Hence, the wait must continue before we rejoice.

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REFERENCES

1. McNamara JA Jr, Brudon WL, Kokich VG. Orthodontics and dentofacial orthopedics. 1st ed. Needham: Needham Press; 2001.
2. Clark WJ. Twin block functional therapy: Applications in dentofacial orthopaedics. St Louis: Mosby; 2002.
3. Baccetti T, Franchi L, Toth LR, McNamara JA Jr. Treatment timing for Twin-block therapy. Am J Orthod Dentofacial Orthop 2000;118:159-70.
4. Mills CM, McCulloch KJ. Treatment effects of the twin block appliance: a cephalometric study. Am J Orthod Dentofacial Orthop 1998;114:15-24.
5. Sussman JB, Hayward RA. An IV for the RCT: using instrumental variables to adjust for treatment contamination in randomised controlled trials. BMJ 2010;340:c2073.

Authors' response

We thank our colleagues for their keen interest in our article. We agree that a mean wear time of 12 hours does not represent full-time wear. As such, we highlighted this as an outcome of the study and referred to

"prescribed" full-time and part-time wear protocols throughout the article and in the conclusion section. Our aim was to compare the responses and compliance to varying wear instructions in a real-world scenario. Clearly, compliance was suboptimal in both groups. This finding is intuitive and resonates with a number of recent studies involving objective wear assessment with removable appliances.[1,2] Although we all hope for diligent, full-time wear of removable orthodontic components, we have yet to meet the unicorn who actually does so.

The sample size calculation was based on detecting a 2-mm difference between the 2 groups as a result of the intervention (not, as the writers intimate, on a total reduction in overjet values). We feel this level of difference between the 2 groups as a result of intervention would indeed be clinically relevant and significant.

It was also suggested that there was a risk of contamination bias, because subjects were recruited from the same peer group. Although this is conceivable, we do not believe this to be likely, because recruitment and subsequent random allocation were done within a large department with a broad catchment area. Though we cannot exclude this possibility, it is highly unlikely that participants were derived from the same peer group. Special measures to mitigate potential contamination bias were therefore not deemed necessary.

Finally, the writers refer to the use of the ANB angle as a measure of skeletal response and suggest the use of articulare gnathion. We did record articulare gnathion for completeness in relation to baseline data. We assessed the skeletal response inferentially using a combination of the ANB value, Pogonion-Sella vertical, and A-sella vertical, which are commonly used techniques for assessment of skeletal response. It is important that a finite number of key cephalometric outcomes be included in orthodontic research studies; an excessive number of outcomes can result in problems related to multiple hypotheses with associated likelihood of false positive outcomes. Moreover, interrelationships do exist between cephalometric variables.

Like the writers, we do not believe that now is the time to rejoice; however, we do feel this research has shed new light on wear regimes and their associated effects. Coupled with the findings from our complementary qualitative study,[3] we continue to advocate near full-time wear during Twin-block therapy. However, armed with the knowledge that removable wear regimes are effective, we now tend to taper the introduction of the appliance during the initial weeks to reduce imposition of the appliances. Moreover, where wear is not forthcoming and the onus of full-time wear is a barrier, we will now suggest graduating to a nights-only regime before considering alternative means of Class II correction. Overall, our findings represent an incremental gain in our appreciation of the effects of wear regimes and the impact of functional appliance therapy; however, as ever, further research is required to better understand this.

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REFERENCES

1. Čirgić E, Kjellberg H, Hansen K, Lepp M. Adolescents' experiences of using removable functional appliances. Orthod Craniofac Res 2015;18:165-74.
2. Schäfer K, Ludwig B, Meyer-Gutknecht H, Schott TC. Quantifying patient adherence during active orthodontic treatment with removable appliances using microelectronic wear-time documentation. Eur J Orthod 2015;37:73-80.
3. El-Huni A, Colonio Salazar FB, Sharma PK, Fleming PS. Understanding factors influencing compliance with removable functional appliances: a qualitative study. Am J Orthod Dentofacial Orthop 2019;155:173-81.

Craniofacial growth spurt in Class I subjects: Data vs conclusions

The study by Montasser in the April 2019 issue (Montasser MA. Craniofacial growth spurt in Class I subjects. Am J Orthod Dentofacial Orthop 2019;155:473-81), reports on the diagnostic performance of the cervical vertebral maturation (CVM) method in the identification of the mandibular and maxillary growth peaks in growing subjects. As in many other studies, longitudinal records from the American Association of Orthodontists Foundation Craniofacial Growth Legacy Collection were analyzed. The author concluded that "...presence of CVM3 would indicate the peak of the growth spurt..." and that the results showed the "validity of