Dear Sir,

Early treatment for severe class II malocclusion

I read Yijin Ren's review of the randomised orthodontic trial by Kitty Tulloch¹ and her colleagues (Evid based Dent 2004; 5:100–101) with interest. This review supported the original authors' finding that, "two-phase treatment started before adolescence in the mixed dentition might not be any more clinically effective than a single-phase treatment started during adolescence in the early permanent dentition".

I personally have reservations about the suitability of randomised trials for orthodontics.² This review reminded me that, "evidence confirms or denies but only logic can explain". Two forms of treatment, Head Gear and Bionator, were provided in the mixed dentition and then compared with a control group that had been left untreated until adolescence at which point all three groups were finished with fixed appliances. Dr Ren does not mention that during the first stage of the treatment the authors reported, "We were so impressed with the progress of the children receiving early treatment that we discussed whether it was ethical to deny the control children". They found, however, that the differences "disappeared when both groups received comprehensive fixed-appliance treatment". We know that fixed appliances are very powerful and to some extent put the teeth and their supporting bone into a 'straitjacket'. Is it possible that the similarities in the comprehensive fixed treatment overwhelmed the differences created by the early treatment? This would give us an alternative explanation for why they all finished with similar results.

Dr Ren may not have been aware that an earlier study by Brin *et al*³ on the same patients had found that the children who had the two-stage treatment showed little root resorbtion (5%) compared with substantial resorbtion (20.4%) in those who received the one-stage treatment. It is also important to mention that in order to reduce the variables, the children in the Brin study were not expanded before the Bionator treatment. Those familiar with functional appliances believe expansion helps the mandible to relocate forward and that lack of expansion might prejudice the result.

Finally, it has long been known that it is relatively easy to permanently influence the facial skeleton in young monkeys; Franchi and colleagues' recent work⁴ confirms that, in humans, treatment needs to begin before the age of 8 years if much skeletal change is desired. A large proportion of Tulloch's 'early' group¹ was older than this.

In conclusion, I think the title of the article, "Very few indications justify early treatment for severe class II malocclusion", might be misleading. Given a broader spectrum of evidence one could equally conclude that, "Severe skeletal discrepancies are best treated before the age of 8 years, avoiding fixed appliances if possible". Unfortunately, orthodontists have become so committed to perfect dental alignment that some of the wider considerations are sometimes ignored.

Yours faithfully,

John Mew

E Sussex, UK

- Tulloch JFC, Proffit WR, Phillips C. Outcomes in a 2-phase randomised clinical trial of early Class II treatment. Am J Orthod Dentofacial Orthop 2004; 125:657–667.
- Mew JRC. Are random controlled trials appropriate for orthodontics? Evid based Dent 2002; 3:35–36.
- Brin I, Tulloch JF, Koroluk L, Philips C. External apical root resorption in Class II malocclusion: a retrospective review of 1- versus 2-phase treatment. Am J Orthod Dentofacial Orthop 2003; 124:151–156.
- Franchi L, Baccetti T, McNamara JA. Postpubertal assessment of treatment timing for maxillary expansion and protraction therapy followed by fixed appliances. Am J Orthod Dentofacial Orthop 2004; 126:555–568.

Dr Yijin Ren the commentary author responds

I appreciate the comments by John Mew and I address his concerns below.

Dr Mew has reservations about the suitability of randomised trials for orthodontics. In the hierarchy of evidence (research-based evidence), the randomised controlled clinical trial (RCT) is at the highest level, second to meta-analysis or systematic review of multiple RCT.¹ Although many research approaches exist and each approach provides its own unique perspective, the RCT is currently considered the most reliable approach. The processes used during the conduct of RCT minimise the risk of confounding factors that could influence the results. Because of this, the findings generated by RCT are likely to be closer to the true effect than the findings generated by other research methods. There could indeed be discussion as to whether it was ethical to deny the control children but, equally, whether it is ethical to apply a treatment philosophy as routine without enough evidence could also be subject to debate. If Dr Mew agrees with me that evidence-based practice² which integrates best scientific evidence with clinical expertise, knowledge of pathophysiology and of psychosocial issues, and decision-making preferences of patients — is the principle to follow in our profession, the use of RCT in orthodontics should not be denied.

Regarding the difference of external root resorption between onestage and two-stage treatment, Dr Mew stated that the children who had the two-stage treatment had little root resorption (5.0%) compared with substantial resorption (20.4%, 10 patients) for those who received the one-stage treatment.³ This statement is not completely true: first, these data are the proportions of children who had more than one incisor with severe resorption. In fact, 5% (two patients) referred only to the functional group, and in the headgear group the proportion was 12.5% (six patients). Thus, 5% cannot be used as representative for the two-stage treatment group. Second, Figure 2 in the paper shows that the proportion of individuals who had mild root resorption was higher in the

functional and headgear groups than in the controls. Referring back to the definition of mild or moderate/severe (more or less than 2 mm of root length, respectively), if one was to draw the line slightly lower the difference between the groups might be much less, or even disappear, in terms of the severity of root resorption. Besides, the proportion of nonresorption in one-stage treatment was between the functional and headgear groups, which means that, in this respect, one-stage and two-stage treatment were similar. Furthermore, as the authors themselves stated, "variables other than overjet reduction and duration of fixed-appliance treatment must play a role in determining the root response to orthodontic forces". Thus, it is not conclusive to use any single known variable to determine the root responses to orthodontic treatment. It is not justifiable to come to the conclusion that onestage treatment induced more root resorption than two-stage treatment.

Dr Mew referred to recent work⁴ stressing that, in humans, treatment needs to begin before the age of 8 years if much skeletal change is desired, and that a large proportion of Tulloch's early group was older than this. Dr Mew may have overlooked the fact that the group in the former study is not comparable with that in the latter — one had Class III malocclusion, the other Class III malocclusion. It has been known for a long time that, for Class III malocclusion, early treatment may be favourable when maxillary expansion and protraction are indicated.^{5,6} This timing cannot be extended directly to Class II malocclusion.⁷

In the end, Dr Mew considered the title to be misleading, suggesting another one, "Severe skeletal discrepancies are best treated before the age of 8 years, avoiding fixed appliances if possible". This argument is at most true for some Class III malocclusions. Putting it in a broader background might be misleading and not justified.

Briefly, my review was intended to introduce the first 10-year RCT with a large sample size in orthodontics testing the justification of a

long-held treatment philosophy. As we all know, RCT are extremely time-consuming and take a great deal of effort. Although the generalisation possible from one RCT is limited, its value and the efforts involved should be complemented and encouraged.

Yours sincerely,

Yijin Ren

Gröningen, The Netherlands

- Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. User's guide to the medical literature: IX. A method for grading healthcare recommendations. J Am Med Assoc 1995; 274:1800–1804.
- Rutledge DN, Grant M. Evidence-based practice in cancer nursing. Introduction Semin Oncol Nurs 2002; 18:1–2.
- Brin I, Tulloch JF, Koroluk L, Philips C. External apical root resorption in Class II malocclusion: a retrospective review of 1- versus 2-phase treatment. Am J Orthod Dentofacial Orthop 2003; 124:151–156.
- Franchi L, Baccetti T, McNamara JA. Postpubertal assessment of treatment timing for maxillary expansion and protraction therapy followed by fixed appliances. Am J Orthod Dentofacial Orthop 2004; 126:555–568.
- Baccetti T, Tollaro I. A retrospective comparison of functional appliance treatment of Class III malocclusions in the deciduous and mixed dentitions. Eur J Orthod 1998; 20:309–317.
- Kluemper GT, Spalding PM. Realities of craniofacial growth modification. Atlas Oral Maxillofac Surg Clin North Am 2001; 9:23–51.
- Chafari J. Timing the early treatment of Class II, division 1 malocclusion clinical and research considerations. Clin Orthod Res 1998; 1:118–129.

Evidence-based Dentistry welcomes letters about articles published in the journal or about evidence-based dentistry in general. Send your letters to: EBD Editor, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London N1 9XW, UK or via e-mail to: ebdeditor@nature.com

Evidence-Based Dentistry (2005) **6**, 53–54. doi:10.1038/sj.ebd.6400331