

## letters

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*Evidence-Based Dentistry* (2002) 3, 86–87. doi:10.1038/sj.ebd.6400134

Dear Sir,

*Kalha AS. Summary. Fluoride-releasing elastomerics reduce enamel decalcification during fixed appliance therapy. Evidence-based Dentistry 2001; 2:101*

I agree with Dr Kalha that this paper is a useful contribution to the vexing clinical problem of demineralisation during orthodontic treatment. I would, however, disagree with a number of points. First, he describes this as a randomised controlled trial, but patients were allocated alternately to receive either fluoride-releasing or non-fluoride-releasing elastics. This is not an accepted form of randomisation.<sup>1</sup>

Second, he states that there were adequate blinding procedures although the assessment was carried out by one of the clinicians who had treated some of the patients and no mention is made of measures to ensure the assessment was carried out blind.

I also dispute the figures in Table 1. According to the original article the number of patients with some demineralisation at the end of treatment was 73% for the control group and 63% (not 26%) for the experimental group. The absolute risk reduction is therefore 10% and the number-needed-to-treat to prevent one case of demineralisation is nine.

The addition of stannous fluoride into orthodontic elastomerics would seem an ideal way of delivering fluoride locally to prevent demineralisation around orthodontic brackets, but I, along with others,<sup>2</sup> have found that it has adverse effects on the properties of the elastomeric material.

Yours faithfully

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1. Altman DG. *Practical Statistics for Medical Research*. London: Chapman and Hall, 1991; p85.

2. Miethke RR. Comment on determination of fluoride from ligature ties. *Am J Orthod Dentofac Orthoped* 1997; 111:33A.

### **Dr Kalha responds:**

I do appreciate detailed appraisal of the commentary and article on fluoride-releasing elastomerics by Dr Benson. The comments are absolutely valid but need to be viewed in perspective. The randomisation is not classic as quoted in the text but generally conforms to the principle of patients receiving a fair exposure to either of the elastomerics and thereby reducing any bias in the study. The issue here is whether absolute randomisation is possible in an orthodontic environment. Various authors have dealt with this issue. Do we ignore the value of a study simply because it does not fit into a textbook ideal?

I have clearly stated that the blinding procedures were adequate. They were not ideal but in the context of the study they seem reasonable. Maybe this is a subjective interpretation of issues.

The problem of demineralisation has to be seen on a tooth surface basis rather than an absolute risk reduction in patients. The significantly lower score per tooth with a 49% difference may be more relevant in the context of white spot lesions as all teeth may not carry brackets.

I would certainly endorse Dr Benson's observations that all studies need to be randomised properly and structured well. Until then, perhaps we should look at the general issues and appreciate the value of a study rather than dismissing it because it does not conform to the ideal. The critics of the evidence-based system endorse the view that we are likely to lose ourselves in numbers. To quote Plato, "Every system destroys itself by an excess of its basic principle." I am sure orthodontics will evolve to an evidence-based speciality. Up to that point, we need to give it a chance.

**Dr A Kalha**  
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## Erratum

As identified by Dr Benson there were errors in the Table in the article **Fluoride-releasing elastomerics reduce enamel decalcification during fixed appliance therapy**. *Evidence-based Dentistry* 2001; 2:101. An amended Table 1 appears below.

**Table 1** Enamel decalcification in control and treated groups

	Fluoride-releasing elastomerics	Control
Patients (n)	45	49
Teeth with decalcification (%)	16	26
Individuals with enamel decalcification (%)	63	73
ARR (%)		10
NNT*		10

ARR, Absolute risk reduction; NNT, number-needed-to-treat.

\*NNT is 1/ARR for proportions or 100/ARR for percentages.