Letter to the Editor

Dear Sir

We refer to the paper by Laustsen *et al.* (2005) that appeared recently in the *IEJ*. We have discussed the study and its conclusion with the authors but we remain concerned that the project was performed without compliance to the instruction for use of Coltosol F.

As manufacturer of Coltosol F, a material clinically proven over more than 30 years of regular and reliable use, we strongly reject the conclusions of the study on the basis of the following:

The hypothesis that Coltosol F is clinically unsuitable came originally from a study carried out by one of the authors when determining bacterial penetration in root filled teeth. As a sealing material for restoration of the access cavity the authors used either Coltosol or zinc oxide eugenol (ZOE). In both groups they observed tooth fractures. The authors concluded that the expansion of Coltosol F was responsible for this. However, they did not consider the root canal sealing material Cavit (an expanding material of similar composition as Coltosol F) which was applied even deeper in the tooth with a disadvantageous and unfavourable C-factor acting as a wedge. This also explains the observation of a tooth fracture in the ZOE group. Thus, even the hypothesis in itself was based on incorrect assumptions.

The study design was selected in such a way as to achieve the desired tooth fractures. The placement of the material in large class II cavities to 1 mm above the cemento-enamel junction is in contrast and in contradiction to the instructions of use for Coltosol F, where it is clearly stated in the section contraindications: 'Temporary filling of cavities which include multiple areas and extend up to or under the gingiva (subgingival)'.

The build-up of the proximal walls with glass ionomer cement emphasizes the tendentious study design. It is neither taught nor recommended. It was chosen with the main motive to cause the material to crack teeth. The authors explicitly admit this in the paper by stating: 'The cavity walls were restored with proximal glass-ionomer restorative material before filling with provisional cement: (i) in order to secure that a hygroscopic expansion of the provisional cement might cause expansion directed in the bucco-lingual direction ...'. It is obvious that a material (GIC) releasing water and simultaneously hindering the induced expansion must lead to false positive results. In open cavities (state of the art) the expansion forces are released.

In the discussion section the authors explained the fact that the (because of the incorrect study design) broken teeth showed a striking different expansion behaviour than the non-broken by 'biological diversity'. At the end of the paper a speculation was made that a failure of the GIC led to the 'irregular slopes'. Under regular conditions these teeth should have been excluded from the study.

Conclusions of a study only hold for the applied conditions. If, nonetheless, somebody wants to generalise the findings, they have to demonstrate the relevance of the design on the real situation. The authors did not do this, obviously because it is not possible. The study design and reality are far apart – they are diametrically opposed to each other. Coltosol F was applied in a contraindicated cavity in an inappropriate technique. Who would, in practice, ever build a temporary filling with a material that exhibits adhesion to tooth structure? After removal one would have to finish the margins to remove residual GIC, thus compromising the fit of the definitive restoration.

As a direct consequence of the publication customers who have been using Coltosol F without any problems whatsoever and to their full satisfaction for years may now feel uncertain and insecure. Therefore Coltène/ Whaledent would like you to publish a statement that corrects the above mentioned findings and conclusions. This statement must explain that the study used methods that are in contradiction to the instruction for use of Coltosol F.

Yours sincerely

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330

Reference

Laustsen MH, Munksgaard EC, Reit C, Bjørndal L (2005) A temporary filling material may cause cusp deflection, infractions and fractures in endodontically treated teeth. *International Endodontic Journal* **38**, 653–7.

Response from authors

Dear Editor

It is generally accepted that a filling material with a substantial expansion due to water uptake might cause fracture when placed in a cavity. That happened when Coltosol F was used as described in our study. In our opinion this information is beneficial to the dental community. In addition, a warning for use of Coltosol F in cavities with thin cavity walls seems justified.

According to the letter, 'incorrect study design' has been used. We assume that this refers to the use of standard MOD preparations with the proximal parts reestablished with glass ionomer cement. Class II cavities are indicated in the instructions for use, and our choice of preparation seems therefore to be justified and not contra-indicated.

Yours sincerely

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