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LETTER TO THE EDITOR

Invalid results because of inappropriate statistical analyses. Treatment recommendations still in question

Wigen TI, Agnalt R, Jacobsen I. Intrusive luxation of permanent incisors in Norwegians aged 6–17 years: a retrospective study of treatment and outcome. *Dent Traumatol* 2008; **24**:612–8.

Dear Editor,

The recently published article by Wigen et al. (1) uses inappropriate statistical analyses. Thus, the results are not valid and therefore the conclusions, which comprise treatment recommendations, are to be rejected.

Following intrusion injuries, the authors predominantly choose to wait for re-eruption, in some instances they extruded the teeth surgically or by orthodontic forces. In their statistical analysis, they compared non-active treatment (waiting for re-eruption) and active treatment (surgical and orthodontic extrusion combined in one group). As statistical methods, they used Fisher's exact test, chi-squared test and Kaplan–Meier analysis. The results in these single factor analyses gave significant correlations between pulp necrosis (PN) and root development ($P = 0.04$, immature better than mature) and PN and treatment ($P = 0.05$; non-active better than active). Infection-related resorption (=inflammatory root resorption) was related to additional crown fractures ($P = 0.02$) and tended to be related to treatment ($P = 0.08$). Replacement resorption (RR) was related to treatment (0.02) and tended to be related to intrusion depth ($P = 0.08$). There were no regression analyses nor any analyses on dependencies of the variables investigated. The authors concluded from the results that 'The best treatment of intruded incisors in 6- to 12-year-old children is to await re-eruption', without any restriction in regard to intrusion depth, root development, bone fracture, gingival laceration, injury to multiple teeth. All these factors had been shown to be related to healing in single factor (2–5) and some of the factors in multiple regression (6, 7) analyses.

However, the conclusions of this study are based on incorrect statistics and have therefore to be rejected for these reasons:

Bias because of invalid statistical methods

The present and former publications (2–7) have demonstrated that healing is significantly related to the treatment method but also to factors like intrusion depth, root development, bone fracture and some more. It was also shown that these factors are related to the treatment method, i.e. the treatment was chosen according to the severity of the trauma. This was presumably the same in this study, as the authors write in the Discussion section that 'There was a tendency to choose either orthodontic or surgical repositioning for completely intruded mature teeth'. This implies that the treatment groups were different, the 'starting point'" (damage to PDL and pulp) was worse for the active treatment group. Thus, there is a severe bias which cannot be resolved by the used statistical methods which only test for one factor at a time. If more than one factor is related to the outcome and factors are even interdependent, more complex statistical tests like regression analyses are required.

Bias because of invalid grouping

The authors write that 'Because of the limited number of orthodontically and surgically repositioned teeth, these were combined and regarded as an active treatment group in the further analysis'. However, a limited number within a group may never be a reason for the combination with another group. To use understandable words: Because I just have two apples I add two watermelons, since both are more or less round and I need a group of four to compare the diameter to that of my 20 oranges… Concerning orthodontic and surgical treatment everything is different between these two groups: the timing (fresh wound versus healed wound), the duration (seconds versus months), the necessity for splinting, the accessibility for a possible root canal treatment, the accessibility for a crown reconstruction, and some more. Thus, the grouping of so different cases sets an undeterminable bias and is therefore not acceptable.

Bias because of unclear indication

There is another aspect that additionally questions the value of this and former studies: Data are given on the commencement of orthodontic extrusion and the duration of extrusion and spontaneous eruption. The median period for complete re-eruption was about 5 months. The orthodontic extrusion mainly started with a delay of several months, in at least one case 8 months after injury. Thus, the treatment was started *after* most other teeth already had regained their normal position. No informations are given on the reason for such a delayed commencement. It may be assumed that the authors only used an orthodontic extrusion if a tooth was in a position different to that it should be, obviously there was no spontaneous eruption up to that time. Thus, the orthodontic extrusion was most probably used to treat a complication (even an ankylosis? Was there an additional treatment like loosening with forceps?) instead of the injury. In such a case, it would be likely, or at least possible, that the outcome is less good. Furthermore, it can be hypothesized that in one of these teeth treated orthodontically months after trauma a pulp necrosis already had developed *before* the start of the orthodontic extrusion. In such a case, the orthodontic treatment may not be accused for that already established pulp necrosis. No information is given on these important and decisive questions. However, the authors are explicitly appreciated for the presentation of these informations, on the commencement of the orthodontic extrusion, despite being incomplete. No other study has referred to that, and thus it may be hypothesized that in all other studies the orthodontic extrusion might in parts have been used to treat a complication instead of the intrusion injury, leaving reduced chances when compared with other treatment options. Additionally, a recent animal experiment revealed that an immediate commencement of orthodontic extrusion gave better results than a delay of just 1 week (8). The commencement of the orthodontic treatment seems to be another obviously decisive factor, which was not considered up to now in clinical studies. If that finding is true, and there is no reason why it should not, all studies in relation to orthodontic extrusion of intruded teeth have to be re-evaluated or discarded.

A short review of the literature and conclusion

The conclusions of the present study are in contrast to two clinical studies in which no differences could be found between the different treatment options (6, 7). Both studies used adequate statistical methods (regression analysis); however, one study also suffered from grouping different treatment options: Waiting for re-eruption and orthodontic extrusion as non-surgical treatments were compared to surgical extrusion (7). On the other hand, the present study is in accordance with a recent clinical study which presented the highest number of cases ever published on intrusion injuries (2–4), and also with another earlier clinical study (5). However, also these studies used inappropriate statistics not considering inter-factor relations and the multivariate situation, and the recent study also used an invalid grouping of cases: Healing-related (!) surface resorption was grouped together with infection related and RR (2–4). Not any of the clinical studies could demonstrate any effect of the treatment method on the survival of the teeth, while one study revealed a significant influence of the intrusion depth (6). Actual animal studies exhibited better healing after orthodontic treatment than after waiting for re-eruption (8), and revealed that immediate (= surgical) repositioning 'neither harmed the repair process nor caused additional damage' in the PDL if compared to waiting for re-eruption (9). In summary, there is not any valid study that would support the hypothesis that waiting for re-eruption would give advantageous healing or survival results compared with orthodontic or surgical extrusion. In contrast, the clinical studies with the most adequate methodology (but a smaller case number) could demonstrate that the results after intrusion are dependent on injury-related (intrusion depth) and patient-related (root development) factors, but not on treatment methods, and the animal studies imply less good healing for non-active treatment, at least in certain cases and within the restrictions of animal studies, which is the opposite of the statement in the present study.

Dental traumatology suffers from small case numbers per trauma type, a very high variance of decisive factors, often being interdependent, and the need of long-term observations. Unfortunately, dental traumatology is still a stepchild in scientific activities, and every clinical study is welcome and really needed to increase our knowledge. Therefore, I acknowledge explicitly all authors who work hard for this goal. However, the (understandable) wish to find the best treatment and to establish treatment recommendations, or even guidelines, may not lead to simplifications in the statistical analyses and the construction of 'significances' which in fact are not there, or cannot be proven yet. The busy or untrained reader tends to take 'significant results', published in a scientific journal, for fact. However, 'facts' based on inadequate studies may – at the best – be irrelevant, but may – at the worst – be completely wrong. Thus, they are dangerous, as they may result in mean clinical outcomes, and they may result in the abandonment of scientific research on the 'mean method'. Therefore, there is an extremely high responsibility to not institute unproven hypotheses as facts.

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Response from the authors

Dear Editor,

We have read the letter regarding our recently published article (1) with interest, and would like to respond to the comments.

The main issue in the letter is that we have used inappropriate statistical analyses, and that the results therefore have to be rejected. To our knowledge, the statistical methods used in the study are appropriate for this type and size of data. The material was small and did not allow multivariate analyses. When performing multivariate analyses, for every independent variable in the model at least 10 cases are needed (2). In this study, only six teeth developed external replacement resorption and thus multivariate analyses were not performed.

In the present retrospective study, we reported the type of immediate treatment and the type and frequency of healing complications. Awaiting re-eruption was the preferred type of immediate treatment in 37 of 51 intruded teeth. We therefore focused on complications after this treatment compared with teeth that had received surgical or orthodontic repositioning. The results are in line with previous results from Andreasen et al. (3) who studied a large sample of teeth with intrusive luxation. No repositioning and awaiting re-eruption in teeth with incomplete root formation resulted in the lowest probability of complications in that study.

Based on findings in this study, we concluded that awaiting re-eruption was the best treatment for intruded incisors in 6- to 12-year-old children. This is in line with the IADT treatment guidelines for intrusive luxations in children (4).

Evidence-based studies in dental traumatology are difficult to conduct because of ethical reasons. Most treatment recommendations are therefore based on observational studies of trauma patients (5).

In agreement with Dr Pohl, we would welcome clinical studies with larger materials allowing multivariate analyses.

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