A clinical investigation of failure rates of different orthodontic bonding agents in a larger orthodontic clinic in Sweden. - A protocol of preliminary results of a controlled prospective study.

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Background

The primary requirement of any bonding adhesive in orthodontics is the ability to secure the attachment to the tooth for the duration of treatment. The successful bonding of orthodontic appliances directly on to the enamel have been greatly influenced by controlled scientific studies towards improving adhesive properties of the material. Buonocure introduced in 1955 the technology that lead to the concept of direct bonding in orthodontics. The Eastman Dental Hospital in New York were the first to the direct bonding technique on patients in 1966. Since then, there has been a rapid development of orthodontic bonding adhesives, and numerous investigations have been published (see background literature).

Most bonding material requires a dry field of operation throughout the bonding procedure. Since moisture control is important, and often difficult, new material with less moisture sensitiveness is preferable. Other aspects of orthodontic bonding has been the possible harmful effect of the use of acidic etching on the enamel. Some new materials have also been developed to be used without etching.

In order to meet the increasing demand for orthodontic treatment in the Swedish population, an efficient and safe bonding agent is required in everyday clinical practice. High failure rates and thus time-consuming rebonding of attachments are not acceptable. The main objective of our ongoing series of investigations is to assess failure rates of different types of orthodontic in a larger public orthodontic clinic, and, to make records of possible side effects. The purpose of the present investigation is to document the use of a new orthodontic adhesive, SmartBond, with respect to safety, efficiency, and possible side effects, and later, to compare these results with the parallel studies on other adhesives.

Aims of the investigation:

The following main objectives were addressed;

- How often do brackets break from the teeth?
- Is Smart Bond easy to handle for the doctor and/or orthodontic assistant?
- Since we work a lot with delegation to the orthodontic assistants: Is SmartBond suitable for working non-assisted ?
- Is the smell strong for the operator or does it irritate the eyes in any way?
- The patients´ reaction to the smell and taste of SmartBond?
- Is it easy to remove excess adhesive?
- How is debonding with SmartBond?

Other investigated adhesives are treated and evaluated according to the same procedure.

Material and method.

Patient samples: The studies are performed in one of the largest orthodontic clinics in southern Sweden with a high demand for orthodontic treatment. The trial was performed according to ordinary clinical conditions, but standardized for scientific purposes. A total of 300 consecutive patients attending the orthodontic clinic will finally be included in the studies. Thus, several malocclusions with a wide range of severity requiring fixed appliances are included.

Study design: Using a split mouth design, the mouth of each patient were divided into quadrants. In each patient the teeth in the maxillary right and the mandibular right belonged to one unit, whereas the maxillary left and mandibular right belonged to another unit. The choice of quadrant for bonding with SmartBond was randomized according to birth day; even or odd. In the initial phase, bracket failure were monitored over the first six months, and documented for each tooth. Failure rate were the calculated for each quadrant and jaw. Where the patient fails to return following bond failure, the time of bond failure should be recorded as the date of the appointment at which bond failure was discovered.

Clinical procedure: All participating orthodontists and orthodontic assistant were instructed to follow the below standardized procedures of the investigation.

- Cleaning and washing tooth surface.
- Placement of a cheek retractor for isolation.
- Bonding according to the *manufacturers instructions*.
- Placement of the initial aligning archwire five minutes after the completion of bonding.
- Written and verbal instruction in relation to appliance care to be given to all patients.
- Patients to return if a bracket becomes loose or if they have any problems with the appliance.
- Treatment interval of 4-6 weeks throughout treatment.

Documentation: A standardized form for the documentation of age, sex, date for start of treatment, placement of brackets, date and tooth of bonding failure were used. In addition signature of operator was recorded.
Failure rate of bonding will be calculated after 6 and 18 months of treatment.

Preliminary results.

Fixed orthodontic appliances have been bonded with SmartBond on approximately 250 patients. 200 of the these patients have now been under treatment för 6-12 months, the remaining patinet 2-4 months.

Bonding: The bonding of metal brackets with Smart bond was quickly and easily performed after a trial period. However, since the adhesive is very fluid there might be a movement of the bracket if you release the pressure too soon. Another significant discovery was that even after the bonding is set between bracket base and tooth excess adhesive is easily removed with hand instruments and it is clearly visible if the tooth surface is dried. This method seemed useful also when bonding was performed by the orthodontic assistant, working without assistance.

Debonding: Numerous patients have been debonded. SmartBond was easily removed from the tooth without the use of rotating instruments, simply by using a scaler. In this way it is more comfortable for the patient.

Adverse effects: No adverse effect of bonding with SmartBond has been observed. No complaints of smell or bad taste has been reported.

Evaluation of bonding failure of 100 consecutive orthodontic patients refereed to the Orthodontic Clinic in need of treatment with fixed appliances in one or both jaws have been bonded with SmartBond have been performed. Some of the assistants bonded only few patients each and also a few received various composite or ceramic brackets. These patients were excluded from this part of the study. The remaining group of patients were in the age of 11-20 years, 37 girls and 37 boys. After 6 month of orthodontic treatment to each patient the records were assembled and the bonding failure rate was evaluated.

Bonding failure: In the upper jaw, there was a bonding failure of 6,9 %. The corresponding result for the lower jaw was 7,8 %.

The frequency of bonding failure did not differ between the left and right sides, nor between the upper and lower jaw. Brackets on central incisors and on premolars were more often rebonded than on the other teeth.

Conclusions

Based upon the results of 200 patients bonded with SmartBond for a duration of 6-24 months, the following conclusions can be made. SmartBond seem to be a reliable orthodontic adhesive to be used in orthodontic practice. A preliminary statistical analysis revealed a bonding failure of approximately 5-6 % within the first year of treatment. A similar study on Transbond and a glass ionomer cement (Fuji Ortho LC) with etching (unpublished results) at the clinic revealed similar rate of failure. Bonding with Fuji glass ionomer adhesive without etching showed a statistically higher failure rate. An important advantage of SmartBond, compared to the other investigated adhesives, was the smooth removal of excess material after bonding, and, the removal of adhesive after debonding. As to date, SmartBond have shown an acceptable level of bonding failure, the material is easy to apply and easily removed. No adverse effects on enamel, nor on the oral mucosa have been observed.

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