Investigation of the Resistance of Select Defense sealant to Toothbrushing abrasion: *Durability study*

Principal Investigator/Institution:

Bennett T. Amaechi, BDS, MS, PhD, FADI
Associate Professor and Director of Cariology
Department of Comprehensive Dentistry, MC 7917
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive, San Antonio, Texas 78229-3900, USA
Tel: 1 210 567 3200/3185; Fax: 1 210 567 4587
Email: amaechi@uthscsa.edu

Sponsor/ Sponsor's representative:

Kenny Gallagher
President
Element34 Technology, Inc.
Phone: 806.780.3400; Fax: 806.780.3404
Email: kenny@e34tech.com

July 30, 2010

OBJECTIVE

1. To compare the durability of SeLECT Defense Primer and SeLECT Defense Enamel Surface Sealant on tooth surface to that of other available products.
2. To compare the durability of SeLECT Defense Primer to that of SeLECT Defense Enamel Surface Sealant.
3. To determine the frequency of application of SeLECT Defense Primer/Sealant that will offer adequate protection to patients against white-spots formation during orthodontic treatment.

METHODOLOGY

Teeth Preparation and experimental grouping

Sound human teeth extracted due to either orthodontic or third-molar impaction reasons and appropriately disposed in various UTHSCSA Dental School clinics, was collected. The teeth were cleaned of debris/stains, and examined using Fiber-optic Transillumination to eliminate teeth with caries, cracks or enamel malformations. The selected teeth were cleaned with pumice to remove the remnants of pellicle. A total of 125 tooth blocks were produced, each bearing either the buccal or lingual surface of a tooth. The blocks were assigned randomly to five experimental groups (25 blocks/group) treated as follows:

Group A. **Control Tooth** - Using non-treated Leopard Light Primer and 3M Transbond XT bracket adhesive.
a. Step 1 – Clean and etch entire facial tooth surface
b. Step 2 – Place Leopard Light Primer on entire facial tooth surface
c. Step 3 – Place Transbond adhesive paste on bracket (*lower incisor brackets or any smallest type*).
d. Step 4 – Light cure bracket to tooth

Group B. **SeLECT Defense Primer** – Using SeLECT Defense Primer and 3M Transbond XT bracket adhesive.
a. Step 1 – Clean and etch entire facial tooth surface
b. Step 2 – Place SeLECT Defense Primer on entire facial tooth surface
c. Step 3 – Place Transbond adhesive paste on bracket
d. Step 4 – Light cure bracket to tooth

Group C. **SeLECT Defense Enamel Surface Sealant** – Using SeLECT Defense Enamel Surface Sealant and 3M Transbond XT bracket adhesive.
a. Step 1 – Clean and etch entire facial tooth surface
b. Step 2 – Place SeLECT Defense Enamel Surface Sealant on entire facial tooth surface
c. Step 3 – Place Transbond adhesive paste on bracket
d. Step 4 – Light cure bracket to tooth

Group D. **Reliance Pro-Seal** – Using Reliance Pro-Seal and 3M Transbond XT bracket adhesive.
a. Step 1 – Clean and etch entire facial tooth surface
b. Step 2 – Place Reliance Pro-Seal on entire facial tooth surface
c. Step 3 – Place Transbond adhesive paste on bracket
d. Step 4 – Light cure bracket to tooth

Group E. **Ultradent Opal-Seal** – Using Ultradent Opal-Seal and 3M Transbond XT bracket adhesive.

a. Step 1 – Clean and etch entire facial tooth surface
b. Step 2 – Place Ultradent Opal-Seal on entire facial tooth surface
c. Step 3 – Place Transbond adhesive paste on bracket
d. Step 4 – Light cure bracket to tooth

Materials preparation

Following the above treatment, the tooth blocks were mounted on 20 mm × 75 mm thermoplastic plates (Thermoforming Material; T & S Dental & Plastics, Myerstown, Pa) with composite resin (AeliteFlo light-cured; Bisco, Inc, Schaumburg, Ill), such that their surfaces flushed with the surface of the thermoplastic plates to permit streamlined movement of the brush filaments. Medium abrasivity toothpaste, Sensodyne (Glaxo-SmithKline, Moon Township, Pa) was used, together with a soft-bristle toothbrush, GUM Classic Straight.

Experimental Procedure

The experiment was conducted with an electrically operated programmable Toothbrushing Machine, which can be programmed to maintain count of the number toothbrushing strokes and the amount of toothbrushing force place on tooth surface during brushing. This programmable device enabled the standardization of the brushing frequency and the brushing force. The toothbrushing machine, consists of 8 translucent plastic brushing wells, which house the cleaning media and teeth, and 8 toothbrush head holders (each weighing 200 grams). Each set of teeth was secured at the bottom of the plastic wells so as to center and expose the tooth surface to the toothbrush filaments during vertical brushing. The toothbrushing machine is limited to vertical motions but has a longer stroke (allowing for more teeth to be brushed per set), and the brush-head pressure and angulations can be varied.

Standard slurry of the dentifrices was prepared by mixing 1 part dentifrice and 3 parts deionized water (9 g:27 ml). The slurry was mixed with a laboratory stand mixer until homogenous. The slurry was poured into the brushing wells, with the tooth submerged in the paste slurry. All sets of teeth were brushed for a total of 20,000 strokes, the equivalent of 2 years of brushing, based on brushing twice daily at 13.7 strokes per surface per brushing. Manley[2] determined average daily brushing at 19.72 strokes per surface per tooth. One forward and backward motion of the brush constitutes two strokes. Each surface was brushed at a toothbrushing force of 2 N (200 g). Although a total of 20,000 strokes were made, the abrasion of the test agents coated on tooth surface by the toothbrushing was monitored as follows. At first, after every 834 strokes (the equivalent of one month of brushing) for a total of 2,500 strokes (the equivalent of 3 months of brushing), then the monitoring was changed to after every 2,500 strokes (i.e. the retention of the products was monitored 3 monthly) for a total of 20,000 strokes.

Measurements

The abrasion (removal) of the test agents on tooth surface by toothbrushing was monitored using Quantitative light-induced fluorescence (QLF™). This is a fluorescence device that can detect the presence of the test agents by eliciting the autofluorescence of the agent. A coated area was highly and more fluorescent than the normal tooth surface, while an abraded or deficient area retained the natural fluorescence of the tooth surface. On each measurement occasion, QLF imaging was carried out following 10-second rinsing with distilled water, and 5-second air-drying using dental air-syringe. The QLF system comprised of a special intra-oral micro-camera device connected to a computer fitted with a frame grabber (Comet, Matrox, Electronic systems Ltd, Quebec, Canada) and to which the QLF software (QLF version 2.0.37, Inspektor Research Systems BV, Amsterdam, The Netherlands) was installed. To visualize and capture the tooth image, white light from a special arc lamp (Philips bv, Eindhoven, The Netherlands) based on Xenon technology is filtered through a blue-transmitting bandpass filter (Philips bv, Eindhoven, The Netherlands) with peak intensity of λ = 370 nm and bandwidth of 80 nm, to provide illumination of the tooth with a blue-violet light with an intensity of 13 mW/cm^2. A dental mirror provided uniform illumination of the tooth, and with the aid of a color CCD-sensor (Sony LS-1P, Tokyo, Japan), which had a yellow-transmitting ($\lambda \geq$ 520 nm) filter (Philips bv, Eindhoven, The Netherlands) positioned in front of it (to filter out all reflected and back-scattered light), the fluorescent image of the tooth was recorded and digitized by the framegrabber and was available for quantitative analysis with the QLF software. Once the fluorescent image of the tooth has been captured and recorded by the PC, analysis of the deficient or abraded area can be initiated by a user-defined patch with borders placed on coated surface surrounding the abraded area. The highly fluorescence radiance values inside the patch are reconstructed through two-dimensional linear interpolation of coated surface values on the patch borders. The decrease in fluorescence was determined by calculating the percentage difference between actual and reconstructed fluorescence surface. Any area with a fluorescence radiance drop of more than 5% of that of coated area was considered an abraded area.

At the first month measurement it was observed that the reliability of the QLF images was not consistent. The percentage loss detected by observation was not readily detected with QLF, and the QLF images were not of sufficient quality to take area measurements. Therefore, measurements were also carried out visually after each time interval. A handheld ultraviolet light was used to disclose and visualize the sealants, and this was much clear. Three observers took the measurements, and the abraded areas were scored as percentage of the entire coated tooth surface. The average of the three scores for each tooth surface was recorded as the score for that surface.

RESULTS and CONCLUSION

After simulated two years of brushing, statistical analysis of the data was performed with SPSS (version 14.0, Chicago Illinois) with the level of significance (α) pre-chosen at 0.05. The result of the visual scoring was used for data analysis due to the poor quality of the QLF images, and thus unreliable data. The Leopard Light primer and the SeLECT Defense primer did not fluorescence, and hence were eliminated from the analysis.

Figure 1 demonstrated the percentage of sealant loss in each group at each assessment time (months). A mixed-models analysis of variance (ANOVA) and Tukey's comparison tests indicated significant differences between SeLECT Defense sealant, Pro Seal and Opal Seal. The difference between any two products was statistically significant at all times, except at first month when SeLECT Defense was not significantly different from Opal Seal. Beyond one month, all three products are statistically different from one another. The Ultradent Opal-Seal proved to be the most resistant to abrasion with an average of 15% loss over 24 months. SeLECT Defense Enamel Surface Sealant had an average loss of 30% over 24 months, while Reliance Pro-Seal was the least resistant to abrasion with an average loss of 55% over 24 months. Some samples even had 90% loss of Pro-Seal.

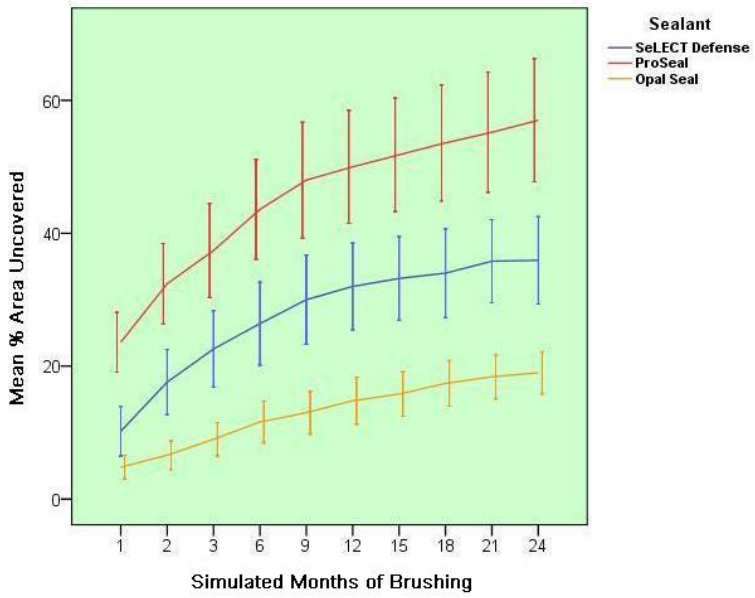

Figure 1

The results of the present study showed that a certain percent of all the sealants investigated were lost within the first month of treatment, and thereafter the lost continued progressively. Orthodontic treatment, in most cases, involves three monthly assessments, and in some special cases monthly. From the result of the present study, it may be advised that the sealants be re-applied at this assessment visits.