Final Report

Marginal bacterial leakage in class I cavities filled with a new resin-modified glass ionomer restorative material.

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The experiment was finished on day 04-12-2013 at 6.30 pm.

Submitted by:
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Purpose. To compare the self-sealing property of a dual-cure recently developed resin
modified glass-ionomer (RMGI) restorative material with a contemporary well established light cure base-liner RMGI material, in class I cavities by means of a bacterial microleakage test. The materials tested were **Group 1**: Activa Fill self-cure mode (Pulpdent); **Group 2**: Activa Fill light-cure mode (Pulpdent) and **Group 3**: Vitrebond (3M).

**Materials and methods**

**Specimen selection and preparation**

For this study, 30 (n=30) human lower second premolars stored at 4°C in 0.2% thymol in normal saline were used. To meet the inclusion criteria, the teeth must be intact, without caries and/or restorations, and present with non-calcified single straight root canals. Additionally, they must have approximate similar lengths and at least a total mesiodistal external diameter of 7 mm at the cemento-enamel junction (CEJ) of the roots. The cusps were completely removed with high-speed diamond burs under water-cooling. In order to obtain a sound flat dentin surface each tooth was horizontally cross-sectioned 1 mm (± 0.5-mm) lower with a water-cooled diamond-impregnated low-speed saw (Isomet, Buehler, Lake Bluff, IL). A second horizontal cross section was obtained 8 mm apical to the CEJ. The teeth were debrided of residual plaque and calculus and examined under a light stereomicroscope at X20 magnification (Carl Zaiss, Oberkochen, Germany) to ensure that they were free of defects. Standardized Class I cavities were prepared in the middle of the flat dentin surface with the help of an acrylic template (4 mm in length bucco-lingually, 2 mm width and approximately 2 mm depth) using flat end carbide burs at high-speed under copious water cooling. The inner angles of the cavities were prepared rounded and the margins were not beveled. The cavities were disinfected with Consepsis (Ultradent Products, Inc. South Jordan, UT USA) followed by copious rinsing with sterile saline.

In order to allow for passage of bacteria that may have penetrated along the margins of the restorations, a pilot experimental perforation was prepared in the center of the floor of each cavity through the remaining dentin so that a channel between the cavity and the root canal was created. For this purpose, each sample was placed on a fixed jig mounted on the base of a mini drill press and the channel was prepared through the root canal using a #0.7 mm diameter sterile parallel-side precision drill mounted in a low speed hand piece. Sterile saline coolant was gently applied during the drilling procedure to minimize the effect of heat generation. The drill was used with light apical pressure with in and out motion. Care was taken to avoid the risk of lateral perforations. To avoid penetration of the
restorative material into the prepared artificial canal during insertion procedures, a sterile hard silicone rod (Raholin, Villa Madero; BA, Argentina) of 0.6 mm in diameter was inserted into the channel from the apical to coronal aspects of the samples until the rod is level with the base of the floor of the cavity preparation. In the event that a specimen cannot be properly prepared, it was discarded and replaced with a new one. The samples were then randomly assigned to three treatment groups of 10 (n=10) samples each. The class I preparations were thoroughly rinsed with sterile oil-free water-spray and dried with filtered compressed air. Care was taken to avoid excessive drying. The cavities were then filled with the test materials without using etching or bonding agents and according to the following protocol:

**Group 1:** (n=10) The cavities were filled following the bulk filling technique (single increment) with ACTIVA Fill (Lot 120612A/120605B) used in his self cure mode and allow for at least 10-12 minutes bench setting. ACTIVA Fill was delivered from a double barrel syringe through an automatic mixing tip, and deposited directly into the cavity preparation. The material was prevented from entering the channel connected to the pulp by means of the silicone rod. Immediately after insertion, the filling material was covered with a celluloid matrix strip to prevent the formation of an inhibited oxygen layer.

**Group 2:** (n=10) In this group, the cavities were filled with ACTIVA Fill and covered with the celluloid matrix strip as described in Group 1. All specimens were then light cured for 40s using a Blue Phase C5 curing unit (Ivoclar, Vivadent AG, Schaan, Liechtenstein) with a light output of 650 mW/cm² at a constant distance of 3.0 mm between the exit window of the visible light source and the top surface of the restoration. This was achieved with the use of a specially devised acrylic jig. The light irradiance of the light-curing unit was checked immediately before each application with the radiometer incorporated into the light-curing unit and if necessary, corrected by internal calibration.

**Group 3:** (n=10) In this group, the cavities were filled with Vitrebond. The Vitrebond powder (Lot N393922) and liquid (Lot N389108) were mixed on a sterile glass slab strictly according to the manufacturers’ instructions and applied into the cavities in a single increment with a sterile ball applicator until the cavity was filled completely. The material was then covered with a celluloid matrix strip and light cured as described in Group 2.

In all Groups, the fillings were finished flush with the horizontal tooth surface. A Gillmore-type needle with a mass of 400 ± 0.5 g and a flat point of 1.0-mm in diameter was used (three sequential measurements at equidistant areas) to ensure that the tested materials were set. After setting, the silicone rods were removed, any gross excess of material was
trimmed with a scaler, and the margins were finished with fine finishing diamonds and flexible polishing disks (3M/ESPE). Before subjected to bacterial leakage, the samples were kept under sterile conditions at 37ºC and 100% relative humidity in a incubator for 24 hours and then stored for another 24 hours in sterile buffer solution at 37ºC after which they were subjected to thermal cycling (2000 cycles) in water baths between 5 – 55ºC with a dwell time of 30 sec. The samples were finally stored once more in a sterile phosphate buffer solution for 5 days at 37ºC.

**Statistical analysis**
The length of time until leakage was detected was compared among groups using the Kaplan-Meier survival analysis. Significant pair wise differences were analyzed using the Log Rank test and the Fischer’s Exact test. The selected level of statistical significance was \( p<0.05 \). The presence of *E. faecalis* was also checked.

**Results** (Table 1)
In Group 1 (ACTIVA fill self cure), turbidity did not occur until 40, 46 and 51 days (one sample each) while no leakage was observed in 7 samples (70%). In Group 2 (ACTIVA Fill light cure), leakage occurred at 55 and 57 days (one sample each), while 8 samples (80%) did not show leakage. In Group 3 (Vitrebond) leakage was observed at 54 and 58 days (one sample each) while 8 samples (80%) did not show leakage. The median survival time (absence of bacterial leakage) could not be estimated for all groups since it was greater than 60 days, the time interval covered by the experiment. Using the Log Rank test and the Fisher’s exact test, no significant differences \( p>0.05 \) were detected among Activa Fill (self and light cure mode), and Vitrebond.

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Observation period (days)</th>
<th>No Leakage</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 – 20</td>
<td>21 – 40</td>
</tr>
<tr>
<td>1. ACTIVA Fill Self cure</td>
<td>10</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2. ACTIVA Fill light cure</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3. VITREBOND light cure</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Final Comments
As per protocol and the cavities for all groups were prepared with 2 mm depth. This was performed in order to standardize the samples because Vitrebond is a base/liner material which according to the manufacturer, Vitrebond must be placed with a thickness of no more than 2 mm. The results obtained with Activa Fill (self and light cure mode) were comparable with those of Vitrebond and suggest that after 60 days the materials are capable of generating an effective seal at the interface material/dentine wall substrate. The effectiveness of the curing depth of Activa Fill or Vitrebond (as a possible factor of influence) immediately after light irradiation, still need to be more extensively investigated.