

## Results of 24-Month Posterior Composite Study

**Study Objective:** While polymerization shrinkage has been indicated as being the single greatest drawback to resin composite as a restorative material, polymerization shrinkage itself is not necessarily a significant problem. Rather, resin composite is capable of developing significant shrinkage stress in cavity preparations that can result in adverse consequences, including fracture of remaining tooth structure, and open restoration margins. This in turn, can cause marginal leakage and staining, recurrent caries, post-operative sensitivity, and ultimately restoration failure. The ability of resin composite to reduce shrinkage stress and provide a sealed restorative-cavity preparation, is considered critical to the clinical success of the restoration. Kerr Corporation has developed a new low-shrinking composite (Premise) designed to reduce polymerization shrinkage. The purpose of this study was to evaluate the ability of Premise resin composite to provide clinically acceptable restorations over a 24-month period. This report provides the outcomes after two years of clinical performance of the restorations.

**Methods and Materials:** Kerr Corporation developed a new low-shrinking composite (Premise) designed to reduce polymerization shrinkage. This evaluation was accomplished using both direct clinical (modified Ryge criteria) and indirect (wear measurement) methods. A training session was conducted for five practitioners and office personnel participating in the study. A total of 50 class 1 and 2 restorations were placed by five PROH practitioners, each completing 10 Premise restorations.

The study teeth were evaluated for vitality prior to restoration by objectively testing for cold response with ice (positive or negative response). Teeth testing negative to cold were additionally evaluated with an electric pulp test (EPT) for vitality (positive or negative response). Only teeth testing vital to cold and/or EPT were enrolled in the study. The patients were asked for their subjective history of temperature sensitivity on each study tooth (positive or negative history). All restorative procedures were performed with rubber dam isolation. The occlusal cavo-surface margins were not beveled. All cavity preparations received the same adhesive system, Optibond All-in-one self-etching dental adhesive (Kerr). The adhesive was light cured for 10 seconds with an Optilux 501 (Kerr) visible light-curing unit. For each restoration, composite was placed in increments of two mm or less in depth and light polymerized for 40 seconds per increment with the Optilux 501 curing unit. All restorations were contoured and finished with finishing diamonds and polished with aluminum oxide impregnated rubber wheels, discs and cups (Kerr). No surface sealant was placed.

Assessments were conducted by the practitioners at the insertion appointment, at the baseline appointment (approximately two weeks after insertion), at approximately one year after insertion, and at approximately two years after insertion. Digital photographs were taken as well as sextant/quadrant polyvinylsiloxane (PVS) impressions. Casts were poured at the OHSU School of Dentistry. The data was analyzed with descriptive statistics. The associations between insertion, baseline, and follow-up for various characteristics were presented using frequencies and percentages in tables. Correlations were computed using Spearman's rank correlation coefficient. All hypotheses were tested using generalized estimating equations (GEE) and exchangeable working correlation model to account for clustering among dentists with different models.

### **Results:**

**Subjective cold.** There was a significant correlation between subjective cold assessment and restoration width at one and two years, but not at baseline. As the restorations became larger, they tended to show more subjective cold response from patients at two years ( $p < 0.001$ ). Interestingly, there was no correlation between restoration depth and subjective cold at baseline ( $p=0.75$ ), one year ( $p=0.38$ ), or two years ( $p=0.23$ ).

**Objective cold.** There was a significant decrease in objective cold from baseline to one year ( $p=0.007$ ), but the change from one year to two years was not significant ( $p=0.19$ ). There was no significant correlation between restoration width and objective cold at baseline ( $p=0.06$ ), one year ( $p=0.66$ ), or two years ( $p=0.62$ ). There was no correlation between objective cold and restoration depth at baseline ( $p=0.28$ ), one year ( $p=0.06$ ), or two years ( $p=0.53$ ).

**Surface roughness.** Sixty-eight percent of study participants did not change their surface roughness ranking from baseline to two-years. The association between surface roughness at baseline and two years was significant ( $p=.05$ ). The association between surface roughness at one-year and two-years was not significant ( $p=0.13$ ). The change in surface roughness from baseline to one year was not significant ( $p=0.10$ ). However, the change in surface roughness from baseline to two years was significant ( $p=0.05$ ). The surface roughness at two years was worse than the baseline assessment.

**Color match.** One restoration failed due to dark discoloration; part of the discoloration was beneath the restoration, and part of the discoloration was on the surface, along with surface pitting. Overall, there was not a significant change in color match from baseline to one year ( $p=0.27$ ), or at two years ( $p=0.97$ ).

**Marginal integrity.** The marginal integrity showed a significant shift ( $p=0.005$ ) from closed to open or ditched margins over the first year of the study. Two restorations (DO of a maxillary first molar, MO of a maxillary second molar) failed due to open margins during the second year of the study. The marginal integrity worsened significantly from baseline to 2-years ( $p<.0001$ ) and from one-year to two-years ( $p<.0001$ ).

**Marginal discoloration.** There was a significant increase in marginal discoloration over the first year of the study ( $p=0.001$ ). There was also a significant increase in marginal discoloration from baseline to two years ( $p<0.0001$ ), and from one year to two years ( $p<0.0001$ ).

**Occlusal anatomic form.** One restoration failed (MO on a maxillary first molar) due to a fracture of a portion of the occlusal and proximal aspect of the restoration during the first year of the study. A second restoration (MO of a maxillary second premolar) failed due to a fracture in the occlusal isthmus of the restoration. Overall, there was no significant change in occlusal anatomic form from baseline to one year ( $p=0.23$ ), or from baseline to two years

*(Continued on page 2)*

## Results of 24-Month Posterior Composite Study *Continued*

*(Continued from page 1)*

( $p=0.80$ ).

**Proximal anatomic form.** One restoration failed (MO on a maxillary first molar; the same restoration as noted in the occlusal anatomic form section above) due to a fracture of a portion of the occlusal and proximal aspect of the restoration during the first year of the study. A second restoration (MODB on a lower first molar) had a fracture of a marginal ridge of the restoration during the first year of the study. Overall, there was no significant change in proximal anatomic form from baseline to one year ( $p=0.83$ ), or from baseline to two years ( $p=0.86$ ).

In addition to the above direct assessments conducted by the practitioners who placed the restorations, indirect evaluations were conducted by OHSU faculty. There was a good association between the direct assessments and the photographic assessments. Analysis of the casts made of the restorations at baseline and at one year supported the clinically acceptable ratings for marginal integrity. There was a trend for increased exposure of the occlusal cavosurface margins between baseline and one year, and further exposure of the cavosurface margins from one year to two years. There was a significant increase in the average wear from baseline to one year ( $p<0.0001$ ), from baseline to two years ( $p<0.0001$ ), and from one year to two years ( $p<0.0001$ ). There was not a significant change in the average wear of the restorations by wear of the tooth in the first year of the study ( $p=0.21$ ), however the change was significant from baseline to two years. In other words, the greater the baseline assessment of the wear of the tooth, the greater the average restoration wear by year two. Similarly, there was a non-significant direct correlation between the width of the restoration and average wear at year one ( $p=0.28$ ), but by year two, the correlation had reached significance ( $p=0.03$ ). There was a significant increase in the average maximum wear from baseline to one year ( $p<0.0001$ ), from baseline to two years ( $p<0.0001$ ), and from one year to two years ( $p<0.0001$ ). Unlike the average wear, there were no significant changes in average maximum wear relative to either the baseline wear of the tooth at year one ( $p=0.41$ ) or year two ( $p=0.19$ ), or relative to the width of the restoration at year one ( $p=0.42$ ) or year two ( $p=0.19$ ).

**Conclusion:** Premise showed acceptable clinical performance after two years of clinical service. The practice-based research network, PROH, provided a valid means to assess the clinical performance of this material under the “real world” conditions of everyday private practices operated by full-time dentists.

**Participating Dental Practices:** Dr. Mark Driver, Dr. Walt Manning, Dr. George McCully, Dr. Ron Selis, and Dr. Scott Travelstead.

Patient 1—#19 MO at insertion appointment.



Patient 1—#19 MO success at 2-year appointment.



Patient 2—#15 MO at baseline appointment.



Patient 2—#15 MO failure at 2-year appointment.

