Principle Investigators:

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Overview of Study Methods:

Subjects in need of Class I and/or Class II restorations were enrolled in two clinical trials conducted in US dental schools. Respective university standards were applied to isolation, anesthesia, caries removal and basic cavity design. All cavity preparations were etched for 15 seconds with 37% phosphoric acid, then rinsed and dried but not desiccated. Prime and Bond® Bonding Agent (DENTSPLY/Caulk, Milford, DE) was applied to all dentin and enamel surfaces and light cured for 10 seconds. SureFil® SDR™ Posterior Bulk Fill Flowable Base (DENTSPLY/Caulk, Milford, DE) was then applied in increments up to 4mm as needed to fill the cavity to the level of the dentin-enamel junction. An experimental low stress micro-hybrid composite resin (DENTSPLY/Caulk, Milford, DE) or EsthetX® HD High Definition Micro Matrix restorative (DENTSPLY/Caulk, Milford, DE) was then layered onto the base to complete the anatomic form of the restoration. Restorations were finished and polished using the Enhance® Finishing System and the PoGo® One Step Diamond Micro-Polisher (DENTSPLY/Caulk, Milford, DE).

Subjects were recalled for evaluation approximately six months, 12 months, 24 months and 36 months following placement of their restoration(s). The clinical parameters relevant to the base material evaluated at Baseline (within one week of placing restorations) and at each recall evaluation were as follows:

- Fracture/Surface Defects – records whether a restoration has fractured, localized or in bulk, or exhibited defects such as voids. Theoretically, bulk fracture could result from deficient properties in the base material.
- Proximal Contact – evaluates the degree of contact obtained with adjacent teeth in the case of Class II restorations. In some situations the contact area of the restoration might consist of base material, either wholly or in part.

- Recurrent Caries – records whether there are recurrent caries associated with the restoration. This parameter is relevant for Class II restorations since the base material is exposed along certain margins of the restoration where recurrent caries may develop.
- Sensitivity – evaluates the presence or absence and severity of post operative sensitivity and may be relevant to the base material.
- Gingival Index – a measure of the inflammatory state of the gingiva adjacent to the restoration. This parameter is relevant to the base material in Class II restorations.

Scoring criteria for these evaluation parameters appear in Appendix 1.

Results:

Number of Subjects/Restorations

	Baseline	6 Months	12 Months	24 Months	36 Months
Total	87/170	81/156	69/131	63/123	49/86

Eighty-seven subjects were enrolled into this clinical trial, receiving a total of 170 Class I and Class II restorations. All restorations were evaluated at the Baseline examination within seven days of the operative procedure. After 36 months, 86 restorations in 49 subjects were available for evaluation representing a recall rate of 56% of subjects and 51% of restorations placed.

Fracture/Surface Defects

	Baseline (%)			6 Months (%)			12 Months (%)			24 Months (%)			36 Months (%)		
	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
TOTAL	167 (98)	3 (2)		145 (93)	9 (6)	2 (1)	124 (94)	6 (5)	1 (1)	116 (94)	6 (5)	1 (1)	80 (93)	4 (5)	2 (2)

Defect free restorations constituted 98%, 93%, 94%, 94% and 93% of the Baseline, six month, 12 month, 24 month and 36 month recall evaluations respectively. The “B” rating indicates a small, repairable fracture or void confined to the occlusal surface. Repairs in this category often require recontouring the restoration. At 36 month recall, a total of four restorations were given this rating. The “C” rating reflects a more extensive defect compared with a “B” rating and requires that the restoration be repaired or replaced. At 36 months two restorations received the “C” rating, one of which required replacement. All restoration defects occurred within the capping agent and were not considered related to the base material.

Proximal Contact

	Baseline (%)			6 Months (%)			12 Months (%)			24 Months (%)			36 Months (%)		
	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
TOTAL	104 (91)	9 (8)	1 (1)	100 (89)	11 (10)	1 (1)	85 (92)	6 (7)	1 (1)	69 (89)	5 (6)	4 (5)	53 (85)	3 (5)	6 (10)

For the five evaluation intervals interproximal surfaces received “A” ratings of 91%, 89%, 92%, 89% and 85% respectively. An “A” rating indicates the optimal level of contact. Clinicians were able to achieve contact in Class II restorations quite readily using the appropriate matrix techniques and contact was by and large maintained throughout the trial. A few restorations decreased in scores while some increased. In addition to the clinical evaluation, Class II study models of approximately two-thirds of the Class II restorations were observed for broadening of contacts per past ADA guidelines for posterior composite resins. Broadening of contacts would indicate interproximal wear was occurring even if not reflected in clinical scores. No such broadening of interproximal contacts was observed on study models at any recall interval.

Recurrent Caries

	Baseline (%)		6 Months (%)		12 Months (%)		24 Months (%)		36 Months (%)	
	A	C	A	C	A	C	A	C	A	C
TOTAL	170 (100)		156 (100)		130 (>99)	1 (<1)	123 (100)		83 (97)	3 (3)

At 36 months, recurrent caries was associated with three restorations. The decay was noted on the occlusal surfaces, adjacent to the capping agent, which was in need of repair. There were no observations of recurrent caries associated with the base material.

Sensitivity – Categorical Method

Baseline (%)				6 Months (%)				12 Months (%)				24 Months			
A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
50 (100)				45(100)				35 (100)				29 (91)	3 (9)		

Sensitivity - VAS

	Baseline	6 Months	12 Months	24 Months
Mean VAS Score	1.85	1.15	1.49	1.42

Sensitivity was scored differently at the two study sites due to differing levels of experience with evaluation methods. At one site, subjects were interviewed in order to record the level of sensitivity they were experiencing at Baseline (5-7 days following treatment) and after six, 12 and 24 months. Mild sensitivity was associated with three restorations but not until the 24 month recall evaluation. Given the low severity and the delayed time of onset, a causal relationship for these three restorations with the base material was considered unlikely. As no relationship between sensitivity and the base material appeared to exist, sensitivity data was not collected at the 36 month recall.

At the other site, a cold stimulus was applied to the tooth and subjects were asked to record their level of sensitivity by placing a mark on a 10 cm line. The line was anchored at one end with a zero, indicating no sensitivity and at the other with a 10, indicating the worst pain imaginable. The length of the interval between 0 and 10 was measured and recorded as the VAS score. Sensitivity was evaluated 5-7 days following treatment and at each recall evaluation. Scores of zero sensitivity are rare in a vital tooth since a cold stimulus is being applied. The mean scores recorded at all evaluation intervals are very low. In a study by Browning (Operative Dentistry, 2007, 32-2, 112), mean VAS scores of 2.1 were recorded following application of a cold stimulus in teeth prior to treatment with Class I or II restorations, presumably a normal response. The sensitivity evaluations at both sites are indicative of no post-operative sensitivity. Again, for this reason, VAS scores were not recorded at the 36 month recall evaluation.

Gingival Index

	Baseline	6 Months	12 Months	24 Months	36 Months
Mean Gingival Index	0.24	0.26	0.30	0.35	0.35

Gingival scores reflected no inflammation to mild inflammation of the gingival tissue in contact with the base material both at Baseline (before treatment) and all recall intervals. Since mild gingival inflammation, a score of 1, is common with or without a restoration in place, these scores indicate an acceptable state of health and showed little or no change on recall examinations. The base material therefore had no adverse effects on the gingival tissue.

Retention

	Baseline (%)		6 Months (%)		12 Months (%)		24 Months		36 Months	
	A	C	A	C	A	C	A	C	A	C
TOTAL	170 (100)		156 (100)		131 (100)		122 (>99)	1 (<1)	82 (99)	1 (1)

At 36 months, one restoration that had a fracture within the capping agent in the marginal ridge area was scored "C" indicating a partial loss of the restoration.

Conclusions:

Based upon the parameters evaluated in these trials, the results presented in this report support the conclusion that the low stress resin when used as a bulk fill base in Class I and II restorations with a conventional universal composite resin as an occlusal capping agent exhibited acceptable performance with respect to safety and efficacy after three years. Several restorations showed minor surface defects consistent with three years of intraoral function. In total, six fractures within the capping agent required repair and one restoration was replaced. There was essentially no post-operative sensitivity related to the use of the low stress resin, and the response of the gingiva in contact with the material was within normal limits. There were no observations of recurrent caries associated with the low stress resin and there were no reports of adverse events throughout the duration of the trial.

APPENDIX 1

CLINICAL SCORING CRITERIA

Fracture/Surface Defects	
A =	None
B =	Localized – clinically acceptable with minor repair
C =	Bulk – replacement or major repair required

Proximal Contact **(Class II restorations only)**	
A =	Dental floss “snaps” through contact
B =	Dental floss meets resistance but doesn’t “snap” – acceptable contact
C =	Dental floss meets little to no resistance

Recurrent Caries	
A =	No caries present
C =	Caries present and associated with the restoration

Retention	
A =	Completely retained
C =	Partially retained

Sensitivity **VAS using cold stimulus** **Interview – use scale below**	
A =	No sensitivity
B =	Mild sensitivity to thermal or pressure stimuli
C =	Significant complaint or spontaneous response
D =	Severe sensitivity, intervention required

Gingival Index	
0 =	Normal gingival
1 =	Mild inflammation, slight change in color, slight edema, no bleeding on probing
2 =	Moderate inflammation, redness; edema and glazing; bleeding on palpation
3 =	Severe inflammation, marked redness and edema, ulceration, tendency to spontaneous bleeding