

## **Principle Investigators:**

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## **Overview of Study Methods:**

Subjects in need of Class I and/or Class II restorations were enrolled into the clinical trials. 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 up to the dentin-enamel junction. An experimental low stress micro-hybrid composite resin (DENTSPLY/Caulk, Milford, DE) or Esthet-X® HD (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 and one year 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 the six month and one-year recalls were as follows:

- Fracture – records whether a restoration has fractured and if so whether localized or in bulk. Theoretically, bulk fracture could result from a deficiency 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 only to the base material in Class II restorations.

Scoring criteria for these evaluation parameters appear in Appendix 1.

## **Results:**

### **Number of Restorations**

	Baseline	6 Months	12 Months
Total	172	154	125

### **Fracture**

	Baseline (%)			6 Months (%)*			12 Months (%)		
	A	B	C	A	B	C	A	B	C
TOTAL	169 (98%)	3 (2%)		147 (97%)	4 (2.6%)	1 (<1%)**	118 (94%)	6 (5%)	1 (1%)***

\* One restoration was not scored at 6 months

\*\* One restoration with a fracture at Baseline and six months was not included in 6-month figures

\*\*\* Restoration not evaluated for other parameters

A “B” rating indicates a small, repairable fracture or void confined to the occlusal portion of the restoration. Three such ratings were recorded at the Baseline examination which was performed approximately seven days following placement.

After 6 months, four restorations were scored “B” and one was scored “C”, indicating a need for replacement. The restoration contained a large void that the investigator chose not to repair but rather replaced the restoration. Ninety-seven percent of the restorations were scored “A”, indicating no fractures or voids. After 12 months six restorations had “B” ratings and there was one additional fracture where there was insufficient bulk of composite resin in a proximal box. None of the fractures or voids was associated with the base material,

### Proximal Contact

	Baseline (%)			6 Months (%)			12 Months (%)		
	A	B	C	A	B	C	A	B	C
TOTAL	109 (92%)	8 (7%)	1 (1%)	92 (89%)	10 (10%)	1 (1%)	81 (94%)	5 (6%)	

Ninety-two, 89 and 94 percent of interproximal surfaces at baseline, six months and one year respectively were given the highest rating of “A”, indicating optimum contact. Clinicians were able to obtain contact for the majority of interproximal surfaces and contact was maintained over a one year period. Both Principal Investigators agreed the results for proximal contact obtained in these trials were similar to their experiences with other composite resin restoratives. To the extent the base material was involved in interproximal contacts, its performance was acceptable.

### Recurrent Caries

	Baseline (%)		6 Months (%)*		12 Months (%)	
	A	C	A	C	A	C
TOTAL	174 (100%)		151 (100%)	1 (1%)**	124 (100%)	

\*One restoration was not scored at 12 months.

\*\* Not associated with base material

There were no observations of recurrent caries associated with the base materials at six months or one year

### Sensitivity – Categorical Method

Baseline (%)				6 Months (%)				12 Months (%)			
A (%)	B (%)	C (%)	D (%)	A (%)	B (%)	C (%)	D (%)	A (%)	B (%)	C (%)	D (%)
50	100%			43	(100%)			33	(100%)		

### Sensitivity - VAS

	Baseline	6 Months	12 Months
Mean VAS Score	1.59	1.18	1.41

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 months. As evident, there was no post-operative sensitivity.

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 after six months and one year. Scores of zero sensitivity are rare in a vital tooth since a cold stimulus is being applied. The mean scores here of 1.59 at Baseline, 1.19 at six months and 1.41 at one year 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.

### Gingival Index

	Baseline (%)			6 Months (%)				12 Months (%)			
	0	1	2	0	1	2	3	0	1	2	3
TOTAL	130 (76%)	39 (23%)	3 (3%)	115 (75%)	35 (23%)			88 (71%)	34 (27%)	2 (2%)	

Gingival scores reflected none to mild inflammation of the gingival tissue in contact with the base material both at Baseline (before treatment) and six months and one year following treatment. Since mild gingival inflammation is common, these scores indicate an acceptable state of health and showed little change on recall examinations. The base material therefore had no adverse effects on the gingival tissue. The scores for severe inflammation were in the same subject and reflected a diagnosis of pregnancy gingivitis.

### Retention

	Baseline (%)		6 Months (%)		12 Months (%)	
	A	C	A	C	A	C
TOTAL	172 (100%)		153 (100%)		124 (100%)	

No restorations were lost.

### **Conclusions:**

The results presented in this report represent 154 restorations evaluated at six months and 122 evaluated at one year. Based upon the parameters evaluated in these trials, the low stress resin when used as a 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 six months. Two restorations required replacement, neither

occurrence being considered the fault of the base material. There was essentially no post-operative sensitivity following its use and there were no reports of adverse events.

## APPENDIX 1

### CLINICAL SCORING CRITERIA

<b>Fracture</b>	
A =	None
B =	Localized – clinically acceptable with minor repair
C =	Bulk – replacement or major repair required

<b>Proximal Contact</b> <b>(Baseline assessment only)</b>	
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

<b>Recurrent Caries</b>	
A =	No caries present
C =	Caries present and associated with the restoration

<b>Retention</b>	
A =	Completely retained
C =	Partially retained

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

<b>Gingival Index</b>	
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