

SDRTM

Smart Dentin Replacement

Clinical Evaluation

DENTSPLY

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PROTAPER® | SPECTRUM® | SANI-TIP® | CAVITRON™ | ASH® INSTRUMENTS

Clinical Evaluation in Posterior Teeth

Study Design

- Two sites: Burgess J and Muñoz C
- 170 Class I and Class II restorations
- 87 patients
- Etch & Rinse with Prime&Bond NT
- SDR applied in increments up to 4 mm
 - up to the dentin/enamel junction
- Micro hybrid composites as cap material

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Baseline and 6 months data

Criteria	SDR - Baseline [%]					SDR – 6 months [%]				
	Σ	alpha	bravo	charl.	delta	Σ	alpha	bravo	charl.	delta
Retention	170	100	n/a	0	n/a	156	100	n/a	0	n/a
Sensitivity	50	100	0	n/a	n/a	45	100	0	n/a	n/a
	mean VAS score: 1.85					mean VAS score: 1.15				
Proximal Contact	114	91	8	1	n/a	112	89	10	1	n/a
Recurrent caries	170	100	0	n/a	n/a	156	100	n/a	0	n/a
Fracture	170	98	2	0	0	156	93	6	1	0

87 patients at baseline; 81 patients at 6 months

Conclusion by Investigators: “There were no failures associated with the base material.”



Baseline and 12 months data

Criteria	SDR - Baseline [%]					SDR – 12 months [%]				
	Σ	alpha	bravo	charl.	delta	Σ	alpha	bravo	charl.	delta
Retention	170	100	n/a	0	n/a	131	100	n/a	0	n/a
Sensitivity	50	100	0	n/a	n/a	35	100	0	n/a	n/a
	mean VAS score: 1.85					mean VAS score: 1.49				
Proximal Contact	114	91	8	1	n/a	92	92	7	1	n/a
Recurrent caries	170	100	0	n/a	n/a	131	>99	n/a	<1	n/a
Fracture	170	98	2	0	0	131	94	5	1	0

83 patients at baseline; 69 patients at 12 months

Conclusion by Investigators: “There were no failures associated with the base material.”



Baseline and 24 months data

Criteria	SDR - Baseline [%]					SDR – 24 months [%]				
	Σ	alpha	bravo	charl.	delta	Σ	alpha	bravo	charl.	delta
Retention	170	100	n/a	0	n/a	123	100	n/a	0	n/a
Sensitivity	50	100	0	n/a	n/a	32	91	9	n/a	n/a
	mean VAS score: 1.85					mean VAS score: 1.42				
Proximal Contact	114	91	8	1	n/a	78	89	6	5	n/a
Recurrent caries	170	100	0	n/a	n/a	123	100	n/a	0	n/a
Fracture	170	98	2	0	0	123	94	5	1	0

83 patients at baseline; 63 patients at 24 months

Conclusion by Investigators: “There were no failures associated with the base material.”



Proximal Contact: 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

Fracture: The “B” rating indicates a small, repairable fracture or void confined to the occlusal surface. Repairs in this category often require recountouring the restoration. Throughout this trial a total of eight 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. During this trial a total of four 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.

