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Clinical Evaluation of the Soft-Start (Pulse-delay) Polymerization Technique in Class I and II Composite Restorations

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Clinical Relevance

Class I and II composite restorations placed with a Soft-Start technique showed no significant changes in post-op sensitivity to cold or any decreased signs of marginal stress.

SUMMARY

The polymerization shrinkage of resin composites may affect restoration quality. A double blind, randomized clinical trial was carried out to compare two curing techniques—Soft-Start (SS) and the plasma arc curing light (PAC). The hypothesis that, delaying the gel point (with SS) improves marginal seal, was tested at alpha=0.05. Also, this report includes two-week, three-month, one-year and two-year results for post-op sensitivity. Twenty informed participants, each needing two Class II and/or complex Class I restorations, gave written consent. All the teeth were trans-illuminated to rule out pre-op crack lines before restoration placement. Fifty Z100-Single Bond restorations (25/SS and 25/PAC) were placed under rubber dam. Protocols: PAC (Control)—incremental curing <2.0 mm, 2000 mW/cm² for 10 seconds for all layers, SS (Treatment)—incremental curing <2.0 mm, 600 mW/cm² for 20 seconds, except the final layer or enamel replacement increment, which was cured as follows—(mW/cm²/time) 200/3 seconds, wait 3 minutes; 200/3 seconds, wait 5 minutes; 600/20 seconds from multiple angles.

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Sensitivity to a standardized cold stimulus was performed preoperatively at 2 weeks and at 3, 12 and 24 months. Patients rated their sensitivity after stimulus by means of a Visual Analog Scale (VAS). In addition, two independent, calibrated investigators evaluated the restorations clinically at each appointment. There were no significant differences in VAS scores between the two groups at any appointment period (two-way ANOVA; $p>0.05$).

Several conditions were defined as indicating marginal stress before the start of the trial. At 24 months, there was no significant difference between the SS and PAC groups.

Conclusion: Within the limitations of this study, Class I and II restorations placed with a SS technique did not show significant changes in post-op sensitivity or decreased signs of marginal stress.

INTRODUCTION

In the late 1990s, several authors suggested that reductions in the rate of initial shrinkage of light-cured restoratives may have clinical benefits for restoration bond-integrity and coined the phrase "Soft-Start" (SS) polymerization.[1-5] This concept proposes to increase pregelation time, so that a slower rate of conversion will allow for better flow of resin with a decrease in contraction stress. SS polymerization may be divided into three separate techniques: stepped, ramped or pulse-delay.[6] A stepped program emits a low irradiance for 10 seconds, then increases immediately to a maximum value for the duration of the exposure. In a ramped program, the irradiance gradually increases from a low value to maximum intensity over a short period, after which it remains constant for the duration of the exposure. Pulse-delay uses a short, low-level burst, a delay for polishing and finally a long exposure at full intensity.[7]

While many laboratory reports suggest that SS polymerization may be beneficial,[1,3,8-13] other studies have found either no difference or a negative influence on various physical parameters.[14-21] Several studies concluded that some of the restorative techniques, which aim at stress reduction, have limited applicability and depend on the materials employed.[22-23] Very few clinical trials are available.[24-27] Three of the reported *in vivo* studies involved the one-year evaluation of Class V restorations, and the only Class II study looked at gap formation after extraction.

PAC lights generate a high-voltage pulse that creates hot plasma between two electrodes in a xenon-filled bulb. Irradiance (up to 2400 mW/cm^2) is much higher than typical Quartz-Tungsten Halogen (QTH) or Light-emitting Diode (LED) lights. The early PAC lights generate very high heat with an inefficient emission spectrum, which required the filters to limit the spectrum to a blue wavelength. Most new PAC lights have broad spectrums and should be absorbed by all photoinitiators. The PAC light was used as a control in the hopes that it would generate maximum marginal stress. The hypotheses, that delaying the gel point by using a SS curing technique would improve the marginal seal by reducing marginal stress during curing and decrease post-operative sensitivity, was tested at the 5% level of significance.

METHODS AND MATERIALS

After IRB approval, 20 informed participants, each needing two Class II and/or complex Class I restorations in terms of incipient or recurrent decay, gave written consent. Two men and 18 women, with a mean age of 32.37 years (ranging from 21 to 57 years), participated in the study. Fifty Z100-Single Bond restorations (3M ESPE, St Paul, MN, USA) were placed under local anesthesia with rubber dam isolation. All the teeth were trans-illuminated to rule out pre-op crack lines. All the restored teeth were in occlusion. Each participant received at least one pair of restorations, and five participants each received two pairs of restorations.

Three calibrated investigators placed 25 pairs of restorations. The restorations were distributed as follows: 16 premolars and 34 molars; 26 Class I and 24 Class II restorations. All the materials were applied according to the manufacturers' instructions. After cavity preparation, the teeth were acid-etched with 35% phosphoric acid (Scotchbond Etchant, 3M ESPE) for 15 seconds and rinsed with air–water spray for about 10 seconds. Excess moisture was blotted dry without air-drying. The bonding agent (Single Bond Plus Dental Adhesive System, 3M ESPE) was applied in two-or-three consecutive coats for 15 seconds and gently agitated with a saturated applicator. The bonding agent was then gently air-thinned for five seconds and light-cured for 10 seconds using the same unit for the different protocols. The Z100 restorative resin (3M ESPE) was then placed in 1.5-2 mm thick increments and light-cured each time using one of two methods. A PAC light-curing unit was used as a control (Arc Light II M, Air Techniques Hicksville, NY, USA) using the following protocols: incremental curing <2.0 mm, 2000 mW/cm^2 for 10 seconds for all layers. A QTH light curing unit (BISCO VIP, BISCO, Inc, Schaumburg, IL, USA) was used with the following protocol: incremental curing <2.0 mm, 600 mW/cm^2 for 20 seconds, except the final layer, which was cured as follows—(mW/cm^2/time) 200/3 seconds, wait 3 minutes; 200/3 seconds, wait 5 minutes; 600/20 seconds from multiple angles (Table 1).

The restorations were finished with fine diamond or carbide finishing burs (Brasseler, Savannah, GA, USA) to remove gross excess, followed by Sof-Lex disks (3M ESPE) and the Enhance finishing system (Dentsply, Konstanz, Germany).

Table 1: *Curing Modes and Curing Time Use*

Groups	Incremental Thickness	Irradiance (mW/cm^2)	Curing Time (seconds)	Waiting Time
Control	<2 mm (all dentin layers)	2000	10	None
Soft-start	<2 mm (all dentin layers)	600	20	None
	Final layer	200	3	3 minutes
		200	3	5 minutes
		600	20	

Table 2: *Marginal Stress Data Broken Down into Teeth and Subject Group*

A. Number of Teeth with Marginal Stress	**PAC**	**Soft-Start**
Signs/symptoms of cracked tooth syndrome	0	0
Severe postoperative sensitivity	0	0
Secondary caries	0	1
Marginal discrepancies	4	7
Interfacial staining	2	9
Total	**6**	**17**

B. Number of Subjects with Marginal Stress	**PAC**	**Soft-Start**
Marginal stress in only one category	6	6
Marginal stress in two categories	0	4
Marginal stress in three categories	0	1
Total	**6**	**11**

Table 3: *2 x 2 Contingency Table to Evaluate the Pair of Restorations by Subjects*

		PAC	
		Marginal Stress	**No Marginal Stress**
Soft-Start	**Marginal Stress**	3	6
	No Marginal Stress	1	8

There was no significant difference between groups.
(Chi-square = 2.286; 1 df; p=0.131).

Follow-up evaluation appointments were scheduled at 2-week, 3-month, 12-month and 24-month intervals. At each evaluation, a standardized cold-water stimulus was applied using a custom-made stent to direct the water to the tooth of interest only. Immediately following application of the cold water, the participant was asked to rate the pain level using a 100 mm Visual Analog Scale (VAS). If the pain was the worst possible, the participant would mark the far right end of the line and, in the absence of pain, the far left end. For pain levels between the two extremes, participants made a mark at a point along the line that best represented their pain. The distance in millimeters from the far left end of the line to the point of intersection was recorded.

A modified Ryge criteria was used for evaluation.[28] *A priori* the authors identified marginal stress as the outcome of interest. Several of the categories typically included in the Ryge criteria have little relevance to determining whether a restoration was well sealed or not. Accordingly, for this study, "marginal stress" was defined as a restoration exhibiting any of the following events within the 24-month period of the study: first, signs and symptoms consistent with cracked tooth syndrome. Such signs and symptoms usually include sensitivity to sugar and air and a painful response caused by biting on a specific location of the tooth or crack. Second, severe post-operative sensitivity. This kind of sensitivity was defined as severe enough to necessitate endodontic treatment and replacement of the restoration. Third, secondary caries. Fourth, interfacial staining. Fifth, marginal discrepancy not present at baseline. Two independent, calibrated investigators clinically evaluated each restoration according to this study's modified Ryge criteria, and they interviewed the participant for signs and symptoms related to marginal stress at each follow-up evaluation, except for the two-week evaluation. The data gathered at the two-week interval was cold test and VAS only.

RESULTS

Marginal Stress

The number of teeth exhibiting marginal stress data is summarized in Table 2. Since the experimental unit was the subject and the restorations were paired, analysis by tooth was not statistically appropriate. The more appropriate analysis would be at the subject level. For eight subjects, neither the SS (Figure 1) nor the PAC (Figure 2) restoration exhibited marginal stress. Three subjects had both SS and PAC restorations exhibiting marginal stress. For six subjects, the PAC restoration exhibited no marginal stress, while the SS restoration did. By contrast, for one participant, the SS restoration exhibited marginal stress, while the PAC did not. Results of the Chi square testing are summa-

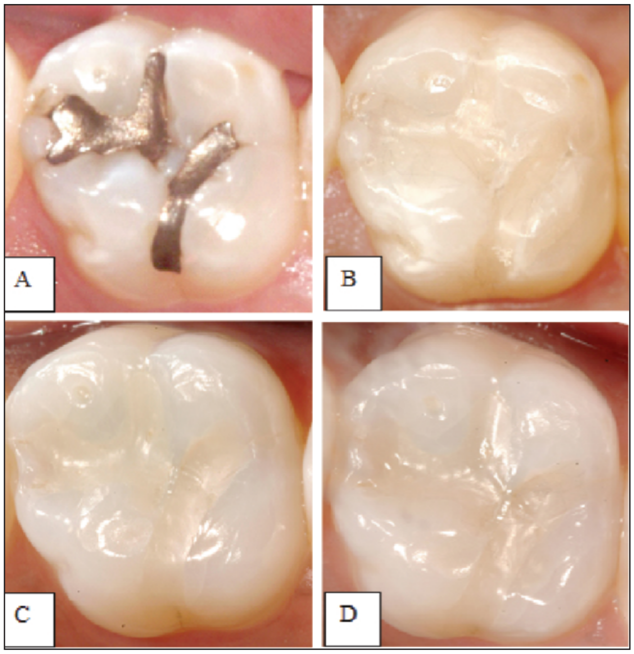

Figure 1: *Soft-start protocol after 24 months. A) Pre-operative view of a complex Class I restoration. B) Immediate baseline view. C) One-year post-operative follow-up. D) Two-year post-operative follow-up.*

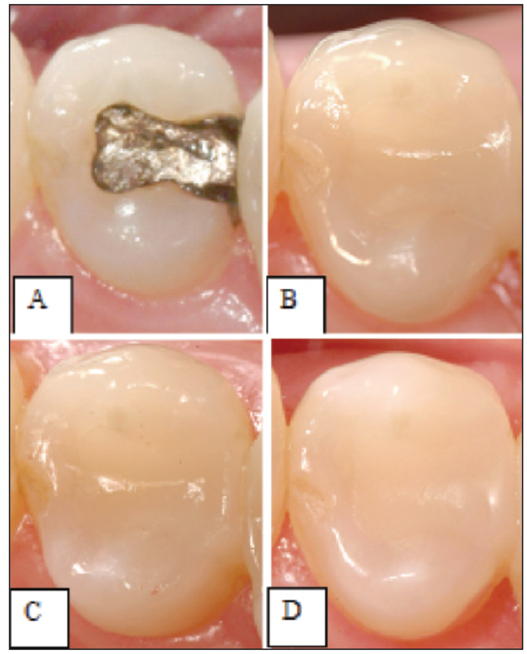

Figure 2: *PAC protocol after 24 months. A) Pre-operative view of a compound Class II DO restoration. B) Immediate baseline view. C) One-year post-operative follow-up. D) Two-year post-operative follow-up.*

rized in Table 3. There was no significant difference between groups (Chi-square = 2.286; 1 df; p = 0.131).

Two restorations failed within the 24-month study period. Both were in the SS Group. One tooth failed due to a Charlie rating for Interfacial Staining. The other restoration was rated Charlie in two categories, Secondary Caries and Marginal Integrity.

Table 4: *Subjective Perception of Pain (VAS scores)*

Column	N	Mean	Std Dev
Soft-Start Group			
2 Weeks	25	-12.1	19.5
3 Months	25	-9.5	26.3
12 Months	25	-12.2	26.4
24 Months	18	-11.7	19.6
PAC Group			
2 Weeks	25	-6.7	22.2
3 Months	25	-13.2	27.1
12 Months	25	-13.7	29.9
24 Months	18	-6.2	27.2

Cold Sensitivity

Subjective perception of pain (VAS scores) is summarized in Table 4. For each evaluation period, the difference in VAS scores was calculated for every subject by subtracting the Pre-operative VAS score from the score at that evaluation period. Accordingly, a negative number indicates a reduction in VAS score and a positive number indicates an increase. Two-way Repeated Measures ANOVA of VAS Scores are summarized in Table 5.

Table 5: *Two-way Repeated Measures ANOVA of VAS Scores*

Source of Variation	DF	SS	MS	F	P
Patient	17	41770.639	2457.096	1.777	0.108
Group	1	277.778	277.778	0.222	0.644
Group X Patient	17	21291.472	1252.440		
Evaluation Period	3	481.222	160.407	0.649	0.587
Evaluation Period X Patient	51	12602.028	247.099		
Group X Evaluation Period	3	99.222	33.074	0.283	0.838
Residual	51	5966.528	116.991		
Total	143	82488.889	576.845		

DISCUSSION

The results of this double-blind, randomized clinical study rejected the hypotheses that delaying the gel point by using a SS curing technique would improve the marginal seal by reducing marginal stress during curing and decrease post-operative sensitivity. Conceptually, it is clinically possible to reduce the composite curing rate by lowering the light intensity used for photo-activation. Alternative curing routines using stepped, ramped or pulsed-delay energy delivery have been developed with the intent of improving restoration interfacial integrity by reducing the composite curing rate, therefore, increasing its flow capacity. Laboratory studies with SS polymerization show contradictory results. While some studies showed improved marginal integrity with non-continuous curing methods, others did not find significant differences between those methods and conventional curing.[1,3,8,13-21]

The authors of the current study could only find four *in vivo* studies evaluating the alternative curing routines. Most studies looked at Class V restorations and resin-modified glass ionomers.[24-27] Brackett and others[24] evaluated the clinical performance of a self-etching adhesive for resin composites over one year. Thirty pairs of restorations were cured using either SS polymerization or high-intensity halogen light. These authors concluded that no significant difference was observed between curing methods.[24] A similar Class V study investigated clinical performance and marginal integrity.[25] This Class V study used a lower light intensity for the first 10 seconds at 150 mW/cm^2, followed by 800 mW/cm^2 for 30 seconds. In terms of marginal integrity or curing mode, no statistical difference was found after one year *in vivo* with the control restoration, which was cured conventionally for 40 seconds at 800 mW/cm^2. This same Class V study showed that the low intensity of 150 mW/cm^2 might have left the material nearly uncured, which means that, after the final cure, a curing mode similar to a conventional cure at full intensity was achieved.[27] Another Class V study investigated the influence of resins, RMGI and different curing methods for polymerization on restorative procedures for non-carious cervical lesions. The overall results showed no difference between the hard-polymerized and soft-polymerized groups.

The only resin composite study published looked at the interfacial adaptation of Class II resin composite restorations with and without a flowable liner.[26] This published study concluded that neither the use of flowable resin composite liner nor the curing mode used influenced the interfacial adaptation.

The pulse-delay technique used in the current study utilized a low-level intensity for a specific network formation at the top surface and allowed the curing process to proceed more slowly in the depth below.[7,29] In the methodology of the current study, the curing protocol called for a total time of at least 8 minutes and 46 seconds, with the majority of that time reserved for the last increment (Table 1). Clinically, this is a long downtime and, from the practitioner's viewpoint, seems time-consuming, especially from the perspective that this technique does not reduce marginal stress and sensitivity. Other reported pulse-delay cure techniques cure composites by providing a low-energy pulse initially (for example, 200 mW/cm^2 for three seconds), followed by a waiting period of three-to-five minutes for strain relief, during which the composite can be finished and polished. The final cure is obtained by exposure to a high-intensity light source of 500 mW/cm^2 for the recommended time.[4] In the methodology of this study, the authors did not incorporate the finishing procedure into the waiting period. Studies have shown that, if finishing is conducted immediately after composite placement, the material might be more readily subject to plastic deformation due to heat generated during the finishing/polishing procedure, as approximately 75% of light-polymerization occurs during the first 10 minutes.[30] The authors of the current study wanted the SS group to have a fair chance to succeed.

Although SS should be able to reduce contraction stress and improve marginal integrity,[21,31] one study found that the advantage of initial slow polymerization obtained by the SS method was offset by a rise in total polymerization shrinkage when final curing was completed at 1130 mW/cm^2.[32] Another area of concern is that the degree of conversion or composite mechanical properties might be compromised by SS curing methods. Reduced stress comes with the price of reduced final conversion.[33] Yap and others[20] reported that curing with the continuous mode resulted in specimens with significantly higher cross-link density than curing with the SS mode. Compared to the aforementioned *in vitro* study, the results of the current study showed no differences between the soft and continuous mode. The clinical implication may be that the top surface layer is cured to a comparable cross-link density with both techniques.

The authors of the current study were able to evaluate 18 pairs of restorations at the end of two years, with the dropout rate being 28%. The authors view this dropout rate as normal, compared to dental clinical studies of the same duration.[34] In other studies, subjects dropping out of clinical trials typically have worse dental outcomes than those who remain. In the current study, subjects were more likely to return if they had problems, since the authors of the current study promised to replace the restorations at no charge. The impact of this drop-out/attrition bias was not assessed.

With previously published Class V clinical studies and confirmation by the Class I/II results of the current study that there is no significance between the two curing techniques, the authors of the current study hesitate to recommend the SS and similar pulse-delay techniques to clinicians. More *in vivo* research is needed to substantiate the potential benefits of this concept.

CONCLUSIONS

Within the limitations of the current study, the authors concluded that restorations placed with a SS technique did not show significant changes in post-op sensitivity or exhibit decreased signs of marginal stress when compared to the plasma arc curing technique. More *in vivo* research is needed to substantiate the potential benefits of this concept.

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