

A CLINICAL STUDY OF SEALANTS POLYMERIZED WITH TWO DIFFERENT  
LIGHT SOURCES

by

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INTRODUCTION

The demand for esthetic and preventive dentistry and the advent of improved oral hygiene standards have resulted in an influx of new and improved dental materials with more efficient ways of curing these materials. Sealing pits and fissures on the occlusal surfaces of posterior teeth has been advocated as a major step in preventing the development of caries.<sup>1-9</sup> Sealant placements, especially in the pediatric population, can be challenging. Management of the pediatric patient, coupled with the need to ensure proper tooth isolation in the placement of sealants can sometimes make this otherwise easy procedure most challenging. Any device that will potentially result in more efficient delivery of service and stress reduction is always welcomed. Light weight, cordlessness, and decreased noise level make the light emitting diode (LED) curing lamps attractive.<sup>10</sup>

Quartz-Tungsten-Halogen (QTH) technology light curing units (LCU) are very popular, but have several drawbacks. These include the limited effective lifetime of the QTH bulb. Additionally, the LCU's bulb reflector and filter degrade over time due to the large amount of heat produced during its operation.<sup>11</sup> Jandt evaluated dental composite materials cured with blue LEDs and concluded that although further studies are needed to fully judge them, there is great potential for future clinical application due to their inherent qualities.<sup>12</sup> Other studies have demonstrated that despite the lower irradiance of the LED light curing units (LCU), when compared to their QTH counterparts, their efficacy is comparable. In dental practice, the potential of using LEDs is promising because their performance should not significantly decrease with time, as happens with QTH LCUs.<sup>13, 14</sup>

Today's clinician must choose a curing light and a resin system from this new and rapidly changing environment. These decisions are often made without solid research evidence to help in the decision making process.<sup>15</sup> This six month clinical study investigated the efficacy of a new LED LCU technology when compared to that of a conventional QTH LCU. This study was designed as a split mouth, randomized clinical study. Sealants were placed and polymerized on contralateral teeth of the same arch utilizing a QTH light source to cure one of the teeth and a new LED light source to cure the other. The light source selection for the first sealant of each pair to be polymerized was made randomly. The same operator placed, and cured the sealants, made impressions and exposed clinical photographs the study. The sealants were evaluated at baseline, three months, and six months by two evaluators.

#### HYPOTHESIS

The hypothesis states that there will be no significant difference in clinical retention and wear between sealants that were polymerized with an LED curing unit and those polymerized with a conventional QTH light curing unit over six months of function in permanent posterior teeth.

REVIEW OF THE LITERATURE

## HISTORY OF LIGHT CURING LIGHTS

Nuva Light by Dentsply/Caulk was introduced to dentistry in 1971 as the first LCU. This light utilized an ultraviolet source to activate the polymerization of resin materials. The ultraviolet light was followed by light curing units utilizing quartz-tungsten-halogen (QTH) bulbs as their light sources. The QTH LCU usually consists of a QTH light bulb filtered by a 100 nm bandwidth filter that transmits radiation in the 400 nm to 500 nm wavelength range.<sup>16</sup> Most composite resins and sealant materials use camphoroquinone (CQ) as a photoinitiator. This photoinitiator is sensitive to light in the blue region of the visible spectrum. Wavelengths effective for the initiation of CQ have been shown to be in the 450 nm to 490 nm wavelength range.<sup>17</sup> Wavelengths outside this range are not as effective. Researchers have indicated that QTH lights used in dentistry today are challenged by the complex resin materials on the marketplace. To effectively polymerize these resin materials, the power of the QTH lamp has been increased, resulting in increased heat generation, which can cause damage to the dental pulp.<sup>18-22</sup> The development of a new light source that generates less heat, yet provides effective curing of resin material, is worth pursuing.

Light emitting diodes (LED) have been proposed as an alternative energy source for curing resins, because the light generated is around the 470 nm range.<sup>14</sup> LED technology has been utilized in the electronics industry as backlights for computers and calculators. The field of medicine has utilized LEDs in multiple areas such as neurosurgery, growth and wound healing.<sup>23</sup> Curing lights utilizing LED have recently

gained popularity in the field of dentistry. LEDs are popular, because they offer low heat generation and a CQ specific emission spectrum.<sup>12, 15</sup> LED lights on the market today include the Freelight (3M ESPE, MN), e-Light (GC America Inc., IL), VersaLux (Centrix Inc., CT), CoolBlu (Dental Systems Intl Inc., FL), and Ultra-Lume2 (Ultradent Products Inc., UT).<sup>24</sup>

Blue LEDs emit a narrow wavelength of light (455 nm to 486 nm), which correlates with the spectral absorbance of the photoinitiator CQ.<sup>25, 26</sup> LEDs are solid-state semi-conductor devices that convert electrical energy directly to light.<sup>27</sup> These semi-conductor chips are enclosed in an epoxy case and form the major component of the LED. When sufficient voltage is applied to the semi-conductor chip, a current starts to flow, resulting in the emission of light.<sup>13, 28, 29</sup> The light produced by LEDs is thought to be more efficient for initiating the cure of dental resins, because the energy is concentrated in the appropriate region of the visible spectrum (Figure 1).<sup>30</sup> Caughman and Rueggeberg stated that older LEDs had to generate energy similar to QTH light to adequately cure some materials.<sup>15</sup> Newer LEDs are made with elements having smaller chips. These smaller chips enable more chips to be placed into the same area and provide much more output than their earlier counterparts to possibly result in a shorter exposure time.

Each light source used in this study had an intensity monitor (radiometer) attached to the base of the unit. The devices measure the intensity of light source ( $\text{mW}/\text{cm}^2$ ) within a limited range of wavelength (400 nm to 525 nm).<sup>31, 32</sup> Laboratory grade radiometers or devices that analyze the spectral curve as well as the intensity of a light can be used to predict the light curing efficiency (Figure 2). One study suggested that

simple clinical radiometers should not be used to compare different light units. Rather, these radiometers should be used to monitor the light units over time for maintenance purposes, i.e. the need for bulb replacement.<sup>31</sup>

The manufacturer reports that the Elipar FreeLight Curing unit (3M ESPE, MN) has an angulated light guide that revolves 360 degrees (Figure 3). It is cordless with variable curing times of 10, 30 and 40 seconds. The diameter of the light guide tip at the output is 8 mm. No cooling fans are required for this light. The power supply is a 4.8 volt nickel-metal hydride storage battery. The operating lifetime of a fully charged battery is 45 minutes. The light intensity is reported to be  $400 \text{ mW/cm}^2$ , and the wavelength range is 440 nm to 490 nm. The length of the unit is 285 mm (11.22"), the diameter, 30 mm (1.18"), and the weigh, 220 g (7.76 oz).<sup>33</sup> LEDs, in light curing units, are driven at high outputs, which may cause them to become hot. This light source utilizes a built-in heat sink in the handle to dissipate the energy.<sup>34</sup>

The Spectrum 800 Curing Unit (Figure 4) is marketed by Dentsply. The light unit has an electric cord. The light intensity of the unit can be adjusted from 300 to  $800 \text{ mW/cm}^2$ , with variable curing times in 10 second intervals. The unit can be pre-set to the most often used light intensity. This unit does have an internal cooling fan. During operation the unit is relatively noisy. The length of the unit is 162 mm, width, 190 mm, depth, 205 mm, and weight, 270 g.<sup>35, 36</sup>

## SEALANT STUDIES

The term pit and fissure sealant is used to describe a material introduced into the occlusal pits and fissures of teeth. This material occludes the deep pits and fissures of susceptible teeth and thereby reduces the impaction of food and collection of

microorganisms, which may contribute to the formation of dental carries.<sup>37</sup> Sealants were introduced as a material to aid in preventing dental caries over a century ago. A classic *in vitro* study done in 1955 by Buonocore demonstrated that using 85-percent phosphoric acid to etch enamel for 60 seconds allowed mechanical bonding of an acrylic resin to the tooth surface.<sup>38</sup> Cueto demonstrated clinically that for a sealant material to be effective in caries prevention, it must remain bonded to the tooth surface. He demonstrated that the capability of acrylic resin to remain bonded to the tooth surface depended on a clean enamel surface, which has been etched to produce microporosities.<sup>39</sup> In 1971, the first dental pit and fissure sealant material, Nuva-Seal (L.D. Caulk), and a LCU utilizing an ultraviolet light source were introduced.<sup>40</sup>

It was recognized early in the development of the sealant technique that moisture contamination either in the form of water or saliva was one reason for failure of sealant materials.<sup>41</sup> Contamination due to saliva can be reduced by the use of proper isolation techniques. Matis showed that a tooth in preparation for sealant placement could be isolated by means of a rubber dam or cotton roll. This clinical study showed that the retention rate of sealants is probably not related to the isolation method, provided that the placement technique was carefully followed.<sup>42</sup> Although proper isolation techniques are key to the success of clinical sealant procedures, Feigal and others demonstrated that a wet surface can effectively retain a sealant if a hydrophilic bonding material is placed prior to the sealant application.<sup>43, 44</sup>

Tooth preparation prior to acid etching and sealant placement varies in clinical practice. Early application techniques for pit and fissure sealant application cleaned the enamel surface to be treated with a pumice and water mixture using a rotary brush.

However, Gillcrist and others demonstrated that dry brushing with a toothbrush as a preparatory step resulted in high clinical sealant retention at 12 months. This retention was comparable to that observed with rotary instrumentation.<sup>45</sup>

Etching time prior to sealant placement has long been a controversy. In the early days, Buonocore used 85-percent phosphoric acid and etched for 60 seconds.<sup>38</sup> Some early Simonsen studies suggested different etching times were indicated for primary and permanent tooth enamel. The recommendations were that primary enamel be etched twice as long as permanent enamel<sup>46, 47</sup> Other later studies have shown that different etching times for different tooth types, primary or permanent, do not appear to affect the retention of fissure sealants on the teeth.<sup>48-51</sup> Today the manufacturer's guidelines and the recommendations of the American Dental Association (ADA) Specification No. 39 for Pit and Fissure Sealants are employed. 3M ESPE, the manufacturer of Clinpro sealant material, recommends the application of etchant to all enamel surfaces to be sealed for a minimum of 15 seconds, but no longer than 60 seconds.<sup>52, 53</sup>

Horowitz reported that after five years there was 42-percent sealant retention. The teeth with partially missing sealants had a lower incidence of caries than the paired, unsealed control teeth that were not sealed.<sup>54</sup> This study led to the belief that even partially sealed teeth are considerably less susceptible to caries than unsealed teeth. Mertz-Fairhurst reported in 1981 that occlusal caries protection on permanent molars is assured if the sealant is completely retained. This 54-month clinical study looked at sealant retention on permanent molars using Delton and Nuva-Seal. Delton was four times more effective in providing protection against pit and fissure caries than Nuva-Seal.<sup>55</sup>

A clinician's judgment is important in determining whether to seal a tooth. One monitoring tool is a caries risk assessment. The National Institute of Health Census Development has reported guidelines in the assessment of caries risk.<sup>56</sup> Tinanoff adopted these guidelines for clinical decision-making of caries management in the primary teeth.<sup>57</sup>

In 1965 a technique that utilized methyl-2-cyanoacrylate (liquid) mixed with poly (methyl methacrylate) powder were mixed together and placed in the pits and fissures of occlusal surfaces. On exposure to moisture the cyanoacrylate polymerized.<sup>58</sup> Sealants are marketed today as filled or unfilled, clear or opaque in color. Newer sealant systems utilize 2, 2- bis [4(2-hydroxy-3-methacryloyloxy-propyloxy)-phenyl] propane (Bis-GMA) resins, which are polymerized either by chemical or visible light activation. Unfilled resin material may penetrate deeper into the fissure system of the tooth surface and may help with mechanical retention of the resin material. Barrie and others conducted a clinical study of 58 children in which half were sealed with PrismaShield, a filled sealant (Dentsply, Caulk, Milford, DE), and the other with unfilled Concise White Sealant (3M ESPE, St. Paul, MN). A community dental service hygienist under field conditions placed the sealants. The results indicated that, over two years, 81-percent of PrismaShield sealants were completely retained as compared to 88-percent of the unfilled Concise White Sealant.<sup>59</sup> Filled sealants require occlusal evaluation and adjustment as a routine part of the application process. Unfilled sealants will adjust on their own when in occlusion with an opposing cusp tip, normally within 24 to 48 hours.<sup>37</sup>

The sealant material used in this study was Clinpro Sealant (3MESPE). It is a light-activated, fluoride-releasing pit and fissure sealant, which is pink in color prior to polymerization, and white after polymerization. This color change is not a "cure"

indicator, per the manufacturer, although a pink color does indicate that the material may not be completely cured. This pit and fissure sealant material is claimed to be an unfilled bis-phenol-A-glycidyl dimethacrylate (Bis-GMA) / triethylene glycol dimethacrylate (TEGDMA) resin sealant. The filler components by weight are <sup>60</sup>:

- a) Tetrabutylammonium TetraFluoroborate 1 percent to 10 percent.
- b) Dichlorodimethylsilane 1 percent to 7 percent.

## WEAR METHODOLOGY

Intra-oral wear has been evaluated using US Public Health Service direct evaluation methods and indirect cast comparison methods. These methods were introduced in the early 1970s and provided qualitative wear measurements.<sup>61</sup> Leinfelder's method is widely used in clinical research involving restorative materials. This method uses six calibrated clinical cast models exhibiting progressive wear in 100 um increments.<sup>62</sup> Bayne and others evaluated Leinfelder's method of evaluating clinical wear and determined that differences between this method and others may be due to differences in shadow production. Bayne further indicated that clinical wear might be systematically underestimated by cast evaluation methods that have well-defined margins. He suggests the use of standardized casts with margin morphology similar to the clinical cast being evaluated for wear.<sup>63</sup>

Mechanical devices such as laboratory scales, stereomicroscopes, commercial and customized profilometers, computerized three-dimensional measuring microscopes, and laser profilometers are all devices that have been utilized in determining occlusal wear. Perry indicated that all these devices resulted in high standard deviations as a result of

inaccurate replicas. Positioning problems and measuring device restrictions were additional problems.<sup>64</sup>

Williams used laser techniques for the evaluation of wear in Class II restorations. This technique determined quantitative changes in the surface topography of the restoration during wear. It involved optical contouring of the tooth surface using a laser and then generating contour maps. A computer-aided method of interpreting these maps provided a measured wear volume that was consistent.<sup>65</sup> Other methods used a laboratory microscope (Clinical Research Associates; CRA system) or a computer-driven stylus (Minnesota System).<sup>66</sup>

Perry and others conducted a study to evaluate restoration wear analysis using the conventional methods (human evaluator indirect cast comparison method, ICCM) and the three-dimensional laser digitizer method. He concluded that systematic differences between the various ICCMs highlight the problem of subjective evaluations of restoration wear. The normalized three-dimensional laser digitizing technique is significantly more effective than subjective evaluations in establishing restoration wear rates.<sup>67</sup>

The wear analyses described so far were mostly used for evaluating restorations with well-defined margins. Wear analysis becomes more challenging when sealant wear is to be analyzed, because sealants are placed on unprepared tooth surface; therefore, there are no defined margins to serve as a reference for wear analysis. In a clinical study, Conry and others quantitatively measured the amount of material placed on a tooth by digitized image analysis. Polyvinylsiloxane impressions of the teeth were taken before and after the restorations were placed. Computerized images of the occlusal surfaces

were superimposed, thus determining the volume of material placed.<sup>68</sup> The same concept was utilized in this study to quantitatively determine sealant wear.

MATERIALS AND METHODS

## SUBJECTS

Thirty-five patients were recruited for participation in this study, which was approved by the IUPUI Institutional Review Board's Human Subjects Review Committee. Once a patient from the pool at the Riley Dental Clinic in Indianapolis, Indiana, was identified as a possible candidate, the dental chart was flagged and contact made with the legal guardian. All guardians in the study were literate, English-speaking adults who accompanied the child for the initial informed consent visit. The guardian and child were given a brief overview of the study protocol, and their participation was solicited. If both the guardian and child agreed to participate, then the guardian was asked to read and sign an informed consent document (Appendix 1). Questions related to the study were addressed, and the guardian and child were assured their participation in the study was voluntary. They were also advised that termination at any point in the study would not be hazardous to the health of the child, and no penalties would be assessed for non-participation.

Patients participating in the study were between the ages of 6 to 21 years, with permanent first or second molars or premolars requiring sealants. Patients included in this study were low-to moderate caries risk.<sup>56,57</sup> The caries risk indicators were adapted from the National Institute of Health's Consensus Development Statement<sup>56</sup> and included:

- a) A clinical examination with the aid of a blunt explorer to help determine occlusal caries.

- b) The patient had no more than one new carious lesion in the past year.
- c) The patient had no white spot enamel lesions.
- d) Dental radiographs as needed to confirm that the patient had no carious interproximal lesions.
- e) Good oral hygiene

Other requirements for the study included:

- 1) At least one pair of unrestored, unsealed, and non-carious, fully erupted contralateral permanent posterior teeth.
- 2) No significant medical problems.

## SEALANT PLACEMENT

Whenever possible, the teeth in this study were isolated by the use of a rubber dam. If rubber dam isolation could not be obtained, then cotton roll isolation was used. Thirty-four patients had sealants placed with rubber dam isolation. One patient had sealants placed with cotton roll isolation and a dry angle. Each paired set of contralateral teeth were isolated identically. The occlusal surface of each isolated tooth was thoroughly cleaned with a brush and water and then air-dried. Scotchbond (3M ESPE) etching gel (35-percent phosphoric acid) was applied to the occlusal surface of each tooth with a disposable brush. Each tooth was etched for 30 seconds (manufacturer recommends a minimum of 15 seconds, but not more than 60 seconds). The etchant was then thoroughly rinsed away. Next, the conditioned occlusal surface was air-dried, and a frosty white appearance of the enamel was confirmed. Clinpro (3M ESPE) sealant material was then carefully applied to the pits and fissures with the Clinpro sealant

syringe needle tip. Then, the sealant was polymerized with a light source for an exposure time of 20 seconds.

One sealant in each test-pair was cured with 3M ESPE's FreeLight LED LCU (Figure 3) and the other with Dentsply's Spectrum 800 QTH LCU (Figure 4) set at 400 mW/cm<sup>2</sup> for an exposure time of 20 seconds each. To minimize the variable of distance of the light source to the tooth, both LCUs were placed in contact with the cusp tips of each tooth during the curing process. Immediately following placement, a clinical photograph of each sealed tooth was made and instructions provided to the guardian and child that included:

- a) Oral hygiene instructions including daily brushing and flossing.
- b) Avoiding eating hard candy and ice.
- c) If the patient needed to return to the clinic for any procedure other than sealant evaluation, the guardian was to advise the clinic staff that the patient was a participant in the sealant study.

At the conclusion of each patient visit, parking garage tickets were validated and an appointment given for a follow-up visit in one week. At the one-week baseline follow-up visits, clinical photographs and polyvinylsiloxane impressions of the sealed teeth were made. The impressions were poured in Stycast 1066 epoxy resin (Emerson and Cuming, Newport, KY) and the resulting models served as baseline records demonstrating the initial coverage and condition of the sealant surfaces.

Two experienced clinical evaluators, who were blinded as to which light unit was used to polymerize each sealant, independently graded the sealants' retention using the method described by Simonsen.<sup>4</sup> Each sealant was classified by the evaluators as either

completely present (Alpha or A), partially present but clinically acceptable (Bravo or B), partially present but not clinically acceptable (Charlie or C), or completely missing (Delta or D) (Table 1).

#### STANDARDIZING THE CLINICAL EVALUATORS

Prior to the start of the study, the clinical evaluators participated in an exercise to standardize the clinical evaluation.<sup>7,40,69,70</sup> Both clinicians were asked to evaluate four sealants using the A to D scoring system (Table 1), and their scores were compared to those of the investigator and an independent, experienced pediatric dentist. Once the standardization process was completed, the clinical examinations for the study proceeded with no discrepancies. Should discrepancies exist that could not be resolved between the evaluators, then the clinician used in the initial standardization process would be asked to give the final score.

#### FOLLOW-UP EVALUATIONS

Patients were evaluated at baseline (one week after placement), at three months, and at six months. Two evaluators using an explorer, a mirror, air, and dry gauze examined the sealed teeth. The evaluators scored the teeth independently, and there was no collaboration prior to evaluation. Based on the previously determined criteria, the evaluator scored each sealant for clinical retention. This score, A to D, was recorded. A clinical photograph and a polyvinyl impression of each sealed tooth were made.

The recall visits were scheduled as follows.

Baseline: One week after sealant placement. Parking garage tickets were validated.

First recall: Three months after sealant placement. Parking garage tickets were validated. The patients were awarded with \$5.00 and an appointment for the six-month recall was made.

Second recall: Six months after sealant placement. Parking garage tickets were validated. The patients were awarded \$10.00 for their participation.

## EVALUATION OF SURFACE WEAR OVER TIME

A hydrophilic polyvinylsiloxane impression (Examix NDS, GC America, Inc. Alsip, IL) material was used to make an impression of each sealed tooth at the follow-up examinations. The tooth was air-dried before a putty wash was expressed on the occlusal surface. Medium body impression material was placed in a sectional tray, which was then used to make the final impression of the tooth. This impression was disinfected, placed in a sealed clear plastic bag, labeled, and transported to the Dental Materials Laboratory.

Each impression was then poured with Stycast 1066 epoxy resin material and allowed to stand for at least 24 hours. The resulting replicas of the sealed teeth were then mounted in purple Playdo material on a glass slide. The replicas were placed on a leveling jig to standardize their position for producing images of the sealant surfaces. The molars were determined to be flat when three cusps tips were parallel to the base of the leveling jig. The premolars were determined to be flat when the leveling jig appeared to be parallel to the desktop. The images were produced and magnified with a Prior Scientific Stereo Zoom Microscope Model 65 at a magnification of X7. The magnified images were then captured by a Polaroid Digital Camera Model DMC1 (Polaroid Co; Cambridge MA) and scanned into SigmaScan Pro Image Analysis software, version 5.0 (Build number 3891). The surface of each replicated sealant was measured by tracing

their images using the SigmaScan program. To minimize the impact of operator error in making the tracings, all images were traced three times, and the designated surface area of each was assumed to be the average of the three. The calculated surface areas of their baseline were then compared to the calculated surface areas at six months postoperatively. The change in each surface area over the six month period represented a quantitative measure of wear for the respective sealant surface. The results of the clinical evaluations and these scanned image analyses were then further analyzed for evidence of correlation.

#### STATISTICAL ANALYSIS OF CLINICAL DATA

The data collected from the clinical evaluations of the sealants at baseline, three months, and six months were analyzed using a cumulative logit model with an explanatory variable for light source and correlations for responses from the same subject. This was fit using PROC GENMOD in SAS version 8.2.

The cumulative logit model incorporates the correlations induced by measuring teeth from the same subject and subsequently allows for statistical comparison of light sources.

#### WEAR ANALYSIS OF SIGMA SCAN DATA

Because many of the initial impressions proved to be inadequate, replicas of only 31 paired teeth in 18 of the 35 patients were acceptable for wear analysis. Two analyses were performed to help determine if the different LCUs had any effect on sealant wear during the six months of function. This was the decrease in area from baseline to six months and the ratio of the decrease in area to the baseline area. Both of these measures

were summarized by the following statistics: the number of observations, the mean, standard deviation, standard error of the mean, and minimum and maximum decrease in sealant surface area.

For each of the two measures, a linear model with fixed effect for light source was fit to the data. To account for similarity induced by teeth coming from the same subject, a compound symmetry covariance structure was incorporated into the model. This means that the correlation of teeth from the same subject is modeled as being the same for all teeth from the same subject. For each of the two measures, a normal probability plot of the residuals and a plot of the residuals versus the predicted values were examined to assess possible deviations from model assumptions of normality and homogeneous error. The residuals from the analysis of the decrease from baseline to six months were highly non-normal. To compensate for this, a log transformation was applied to the measures of decrease, and the linear model was refit to the log transformed data. Least square means obtained from the linear model were compared for assessing significant differences between light sources.

#### ANALYSES OF MOLARS VERSUS PREMOLARS.

Eight subjects contributed nine pairs of molars and 10 subjects contributed 22 pairs of premolars. Molar and premolar data were analyzed separately. Two outcomes were analyzed for the effect of light source, namely, the decrease in area from baseline to six months and the ratio of the decrease in area to the baseline area. Both of these measures were summarized by the following statistics: the number of observations, the mean, the standard deviation, standard error of the mean, and the minimum and maximum areas.

For each of the two measures, a linear model with fixed effect for light source was fit to the data. To account for similarity induced by teeth coming from the same subject, a compound symmetry covariance structure was incorporated into the model. This means that the correlation of teeth from the same subject is modeled as being the same for all teeth from the same subject. For each of the two measures, a normal probability plot of the residuals and a plot of the residuals versus the predicted values were examined to assess possible deviations from model assumptions of normality and homogeneous error. The residuals from the analyses of the decrease from baseline to six months were highly non-normal. To compensate for this, a log transformation was applied to the measures of decrease, and the linear model was refit to the log transformed data. Least square means obtained from the linear model were compared for assessing significant differences between light sources.

#### CLINICAL RELIABILITY

The six months of clinical data collection indicated that examiners were very consistent in their evaluations. There were no discrepancies in the scores reported by the evaluators over the six months of clinical evaluation. Also, there were no inherent biases, because the evaluators were blinded on the light source that was used in polymerizing the sealant. Clinical photographs and impressions of the sealed teeth were readily available for the examiners at all recall evaluations.

RESULTS

## SEALANT EVALUATION AT BASELINE (ONE WEEK FOLLOW-UP)

Seventy-three pairs of sealed teeth were evaluated at baseline. For the teeth polymerized with the QTH light source, 71 teeth received a score of A (97.3 percent), two received a score of B (2.7 percent). Sixty-four teeth polymerized with the LED light source received a score of A (87.7 percent), and nine received a score of B (12.3 percent) (Table II). The estimated odds ratios and the p-values for the test of a non-zero difference of the log odds are listed (Table III). The estimate of 4.99 for the odds ratio at time 0 is interpreted to mean that the odds of being excellent for the QTH light source are nearly five times the odds of being excellent for the LED light source. At three months and six months, the odds of being excellent for the QTH light source are about 2.2 times the odds of being excellent for the LED light source.

At baseline, the QTH light source had marginally significant greater odds of being excellent as compared to the LED light source (p-value = 0.05001). At time three months and six months, there was no statistical difference between the light sources in the odds of being excellent. This is also seen by the 95-percent confidence intervals for the true odds ratios, because each of the confidence intervals incorporates 1 (Table III).

## THREE-MONTH EVALUATION

Thirty-three patients returned for the three-month follow-up visit. For the QTH light, 67 sealants received a score of A (93.1 percent), and five received a score of B (6.9 percent). For the LED light, 62 received a score of A (86.1 percent), nine received a

score of B (12.5 percent), and one received a score of C (1.14 percent) (Figure 5, Table II).

#### SIX-MONTH EVALUATION

Seventy-two pairs of sealants from 32 patients were evaluated at the six-month follow-up visit. For the QTH light, 66 sealants received a score of A (91.7 percent), and six received a score of B (8.3 percent). For the LED light 60 sealants received a score of A (83.3 percent), 11 sealants received a score of B (15.3 percent), and one sealant received a score of C (1.14 percent) (Figure 5, Table II).

#### WEAR EVALUATION

Mean decrease in sealant surface area for all molars and premolars from baseline to six months was greater for LED light than for QTH light (Table IV). Preliminary analysis of the data revealed strong deviation from the assumption of normality, part of the linear model. To correct this, the log-transformed data were analyzed (Table V). Residual plots revealed that the model assumptions of normality and homogeneity were not violated, which implies that the test for statistical differences in the least square means is valid. The comparison of the least square means of log decreases (Table VI) shows no significant differences between the two light sources in mean log decreases.

The ratio of the decrease to the baseline area was also analyzed (Table VII to Table IX). Mean ratio for the QTH light was 0.26, while for the LED light the mean ratio was 0.30. In other words, the QTH light decreased on average 26 percent of the baseline area, whereas LED light decreased on average 30 percent of the baseline area. Residual plots revealed no deviation from model assumptions of normality or homogeneity of

variance. Comparison of least square means obtained from the model reveal no significant differences in the fractional decrease in area for the two light sources.

#### ANALYSIS OF SIGMA SCAN RESULTS BY TOOTH TYPE; MOLAR SEALANT DECREASE

For molars, mean sealant decrease from baseline to six months was greater for the LED light than for the QTH light (Table X). The log decrease was analyzed, because preliminary analysis of the sealant area decreases showed residuals, which violated the model assumption of normality (Table XI). The statistical comparison of light source means was made on the log transformed data. The comparison of the least square means of log decreases showed marginally significantly greater decrease for the LED group (Table XII to Table XIII).

#### RATIO OF DECREASE TO BASELINE

For molars, mean ratio of decrease in area from baseline to six months was greater for the LED light than for the QTH light. Statistical comparison of the least square means showed no significant difference between the two light sources in the mean ratio of decrease in area to baseline area (Table XIV to Table XVI).

#### PREMOLARS SEALANT DECREASE

For premolars, mean decrease from baseline to six months was only slightly greater for the LED light than for the QTH light (Table XVII). The log transformed data were analyzed for statistical comparison, because preliminary analysis of the decreases revealed that the model assumption of normality was violated (Table XVIII to

Table XIX). The comparison of the least square means of log decreases showed no significant difference between the two light sources (Table XX).

#### RATIO OF PREMOLAR SEALANT AREA DECREASE TO BASELINE

For premolars, the mean ratio for the QTH light was 0.26, while for the LED light the mean ratio was 0.27. Comparison of least square means obtained from fitting the linear model revealed no significant difference between the light sources (Table XXI to Table XXIII).

TABLES AND FIGURES

TABLE I

Criteria for clinical evaluation

Rating	Retention	Surface Roughness	Marginal Integrity
A (Alpha)	Sealant present. in all pit and fissures	Smooth sealant surface Good adaptation	sealant smooth and confluent with tooth surface.
B (Bravo)	Sealant present, in all pit and fissures	Sealant surface slightly rough or pitted.	Explorer catches
*C (Charlie)	Missing or Loss sealant.	Voids, deeply pitted sealant.	Explorer penetrates or displaces the sealant.
* D (Delta)	Sealant Missing	Sealant Missing	Sealant Missing

\* Rating of C or D indicated that the sealant was clinically unacceptable. The sealant was replaced. This tooth maintained its C or D rating throughout the study. No further evaluation was done on this tooth.

TABLE II

Percent response by time and light source

Time	Light Source	Response	COUNT	PERCENT
0	QTH	A	71	97.3
0	QTH	B	2	2.7
0	LED	A	64	87.7
0	LED	B	9	12.3
3	QTH	A	67	93.1
3	QTH	B	5	6.9
3	LED	A	62	86.1
3	LED	B	9	12.5
3	LED	C	1	1.4
6	QTH	A	66	91.7
6	QTH	B	6	8.3
6	LED	A	60	83.3
6	LED	B	11	15.3
6	LED	C	1	1.4

TABLE III

Odds ratios by time point\*

Label	time	Estimate	StdErr	LowerCL	UpperCL	p_value**
QTH vs. LED	0	5.00	4.10	1.00	24.92	0.05001
QTH vs. LED	3	2.18	1.28	0.70	6.90	0.18369
QTH vs. LED	6	2.22	1.10	0.84	5.90	0.10918

\*odds of A for QTH vs. odds of A for LED.

\*\*p-value from analysis of log odds.

TABLE IV

Summary statistics for decrease in sealant area ( $\text{mm}^2$ ) as measured by Sigma Scan

Light	N	Mean	Std dev	Std error	Min	Max
QTH	31	2.29	2.25	0.40	0.07	9.22
LED	31	3.16	3.03	0.55	0.27	12.15

TABLE V

Analysis of decrease in sealant area ( $\text{mm}^2$ ) as related to light source

Light	Estimate	Std Error
QTH	0.4012	0.2230
LED	0.7566	0.2230

Model: log decrease = light source repeated tooth / subject = patient types = cs  
Least square mean estimates for light source.

TABLE VI

Analysis of decrease in sealant area ( $\text{mm}^2$ ) as related to light source

Light	Light	Estimate	Std Error	p-value
QTH	LED	-0.3554	0.2347	0.1558

Model: log decrease = light source repeated tooth / subject = patient types = cs  
Model based comparison

TABLE VII

Summary statistics for ratio (decrease in area ( $\text{mm}^2$ ) / baseline area) by light source

Light	N	Mean	Std Dev	Std Error	Min	Max
QTH	31	0.26	0.16	0.03	0.01	0.60
LED	31	0.30	0.16	0.03	0.04	0.62

TABLE VIII

Analysis of ratio (decrease in area (mm<sup>2</sup>) / baseline area (mm<sup>2</sup>) as related to light source

Light	Estimate	Std Error
QTH	0.26	0.04
LED	0.30	0.04

Model: ratio = light source

Repeated tooth / subject = patient type = compound symmetry

Least square mean estimates for light source

TABLE IX

Analysis of ratio (decrease in area (mm<sup>2</sup>) / baseline area (mm<sup>2</sup>) as related to light source

Light	Light	Estimate	Std Error	p-value
QTH	LED	-0.04	0.04	0.2747

Model: ratio = light source

Repeated tooth / subject=patient type=compound symmetry (cs)

Model based comparison

TABLE X

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type:  
molars; summary statistics for decrease in area ( $\text{mm}^2$ ).

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	9	3.57	3.59	1.20	0.07	9.22
LED	9	6.30	3.82	1.27	1.43	12.15

TABLE XI

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type:  
molars; summary statistics for log decrease in area.

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	9	0.47	1.64	0.55	-2.63	2.22
LED	9	1.65	0.71	0.24	0.36	2.50

TABLE XII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: molars

Light	Estimate	Std Error
QTH	0.4685	0.4279
LED	1.6409	0.4279

Model: log decrease = light source  
Repeated tooth / subject = patient = cs  
Least square means estimates for light source.

TABLE XIII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: molars

Light	Light	Estimate	Std Error	p-value
QTH	LED	-1.1724	0.5622	0.0755

Model: log decrease = light source  
Repeated tooth / subject = patient = cs  
Model based comparison

TABLE XIV

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: molars;  
summary statistics for ratio (decrease in area / baseline area)  
by light source

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	9	0.25	0.23	0.08	0.01	0.60
LED	9	0.39	0.19	0.06	0.11	0.62

TABLE XV

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: molars

Light	Estimate	Std Error
QTH	0.2508	0.07246
LED	0.3869	0.07246

Model: ratio = light source  
Repeated tooth / subject=patient type =cs  
Least square means estimates for light source

TABLE XVI

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: molars

Light	Light	Estimate	Std Error	p-value
QTH	LED	-0.1361	0.08895	0.1698

Model: ratio = light source  
Repeated tooth / subject = patient type = cs  
Model based comparison

TABLE XVII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars; summary statistics for decrease in area ( $\text{mm}^2$ )

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	22	1.77	1.17	0.25	0.25	4.39
LED	22	1.87	1.27	0.27	0.27	4.56

TABLE XVIII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars; summary statistics for log decrease in area

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	22	0.33	0.76	0.16	-1.39	1.48
LED	22	0.35	0.82	0.18	-1.32	1.52

TABLE XIX

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars

Light	Estimate	Std Error
QTH	0.3469	0.1897
LED	0.3681	0.1897

Model: log decrease = light source  
repeated tooth / subject patient type = cs least square  
means estimates for light source

TABLE XX

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars

Light	Light	Estimate	Std Error	p-value
QTH	LED	-0.02117	0.2209	0.9257

Model: log decrease = light source  
 Repeated tooth / subject = patient type = cs  
 Model based comparison

TABLE XXI

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars

Light	N	Mean	Std Dev	Std error	Min	Max
QTH	22	0.26	0.13	0.03	0.06	0.51
LED	22	0.27	0.13	0.03	0.04	0.55

Model: log decrease = light sources  
 summary statistics for ratio (decrease in area / baseline area)  
 by light source

TABLE XXII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars

Light	Estimate	Std Error
QTH	0.2632	0.02968
LED	0.2653	0.02968

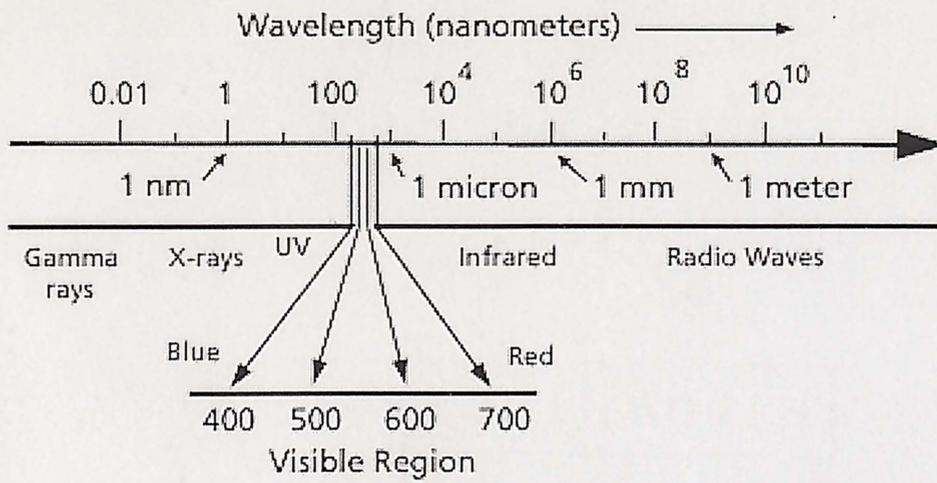
Model: ratio = light source  
 repeated tooth / subject = patient type = cs  
 least square means estimates for light source

TABLE XXIII

Analysis of mean decrease in area ( $\text{mm}^2$ ) by tooth type: premolars

Light	Light	Estimate	Std Error	p-value
QTH	LED	-0.00213	0.03876	0.9574

Model: ratio = light source  
repeated tooth / subject = patient type = cs  
model based comparison



### Electromagnetic Spectrum

FIGURE 1. Electromagnetic spectrum.<sup>30</sup>

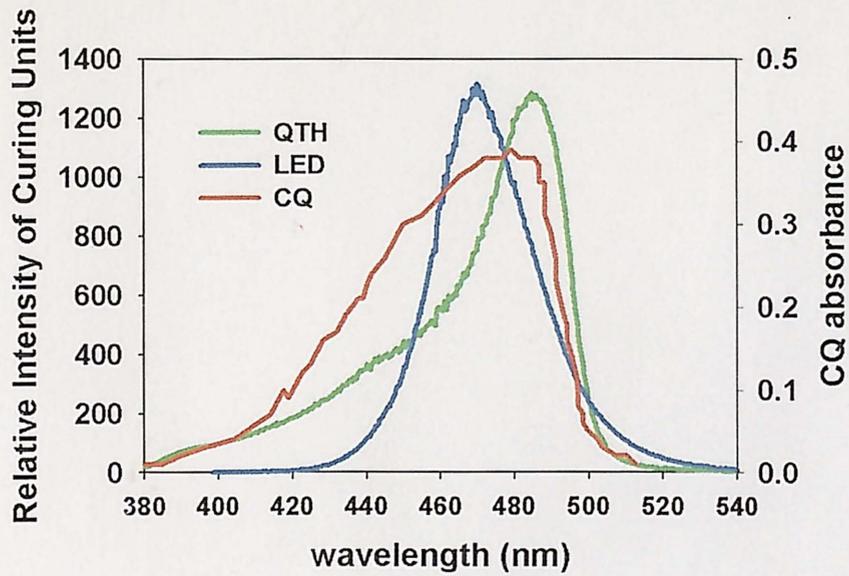


FIGURE 2. The emission spectra of FreeLight and Spectrum 800 lights

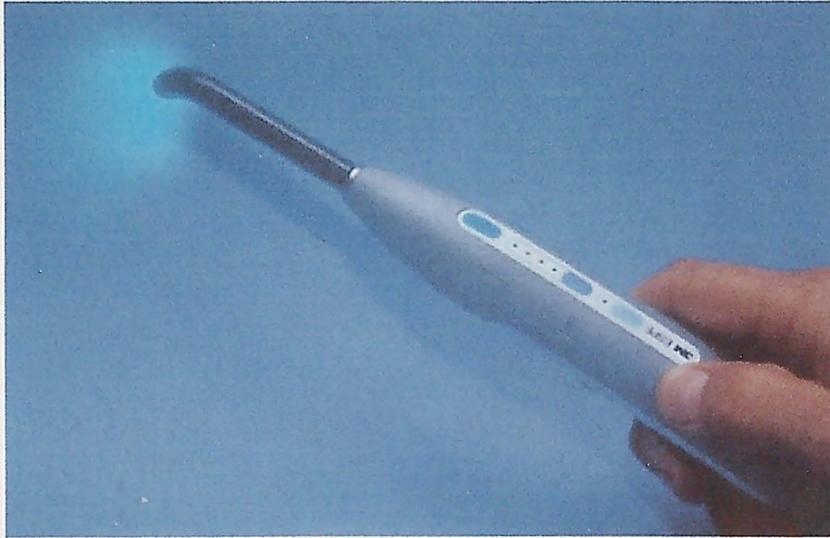


FIGURE 3 3M ESPE Freelight:  
LED light curing unit.<sup>33</sup>



FIGURE 4. Spectrum 800: QTH light curing unit.

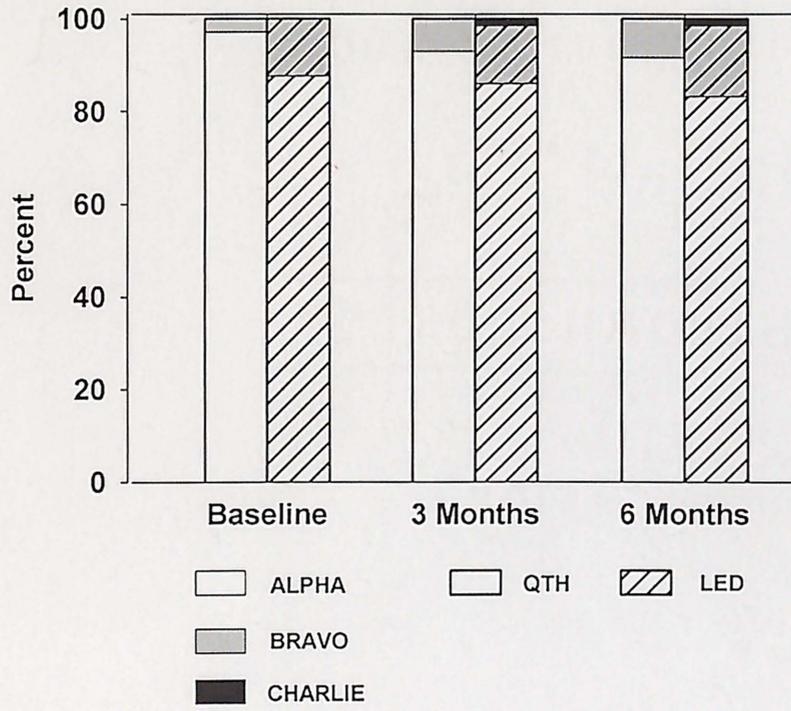


FIGURE 5. Percentage response by time and light source

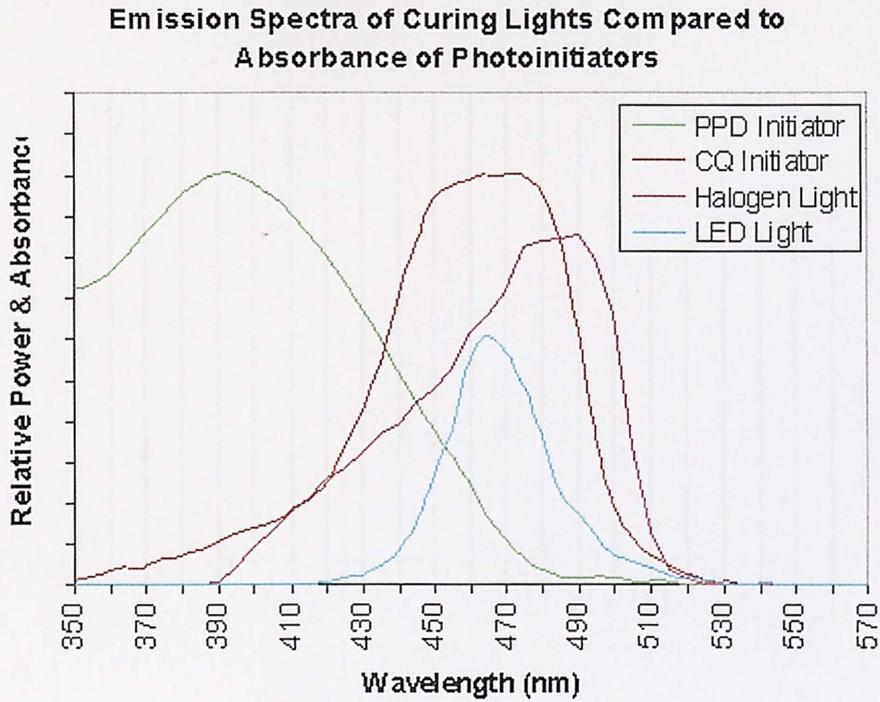


FIGURE 6. Emission spectra of curing lights compared to absorbance of photoinitiation.<sup>34</sup> \*\*

**\*\* This data is representative only and was not generated by the QTH or LED unit used in this study.**

DISCUSSION

At baseline all sealants were present. Two sealants cured with the QTH light received a score of B due to voids noted clinically in the sealant. However, the margins were intact, and the sealants were still considered clinically acceptable. The LED light group had seven sealants receiving a score of B at baseline.

The following explanations are offered as possible reasons voids were detectable in the sealants cured with LED and QTH at baseline: a) air entrapment when the sealant material was expressed on the tooth prior to polymerization; b) unrecognized saliva contamination of the etched tooth; c) water droplets from the air-water syringe during the drying phase just prior to sealant placement.

Care was taken at each stage of the cleaning and application process of the sealants to ensure that the tooth was thoroughly cleaned and dried prior to sealant placement. No saliva contamination was suspected because a well-placed rubber dam remained through-out the procedure. In one case the sealants were placed on teeth in the maxillary arch utilizing cotton rolls and dry angles to maintain a dry field.

The sealants were applied with the needle syringe tip provided with the Clinpro's sealant material. This fine needle tip enabled a thin layer of sealant material to be expressed into the pits and fissures of the teeth. No noticeable bubbles were seen in the sealant material prior to polymerization. Unrecognizable technical error during sealant placement remains a possible explanation for the present of voids at clinical evaluation.

Polymerization of the sealant material will be affected by factors such as the intensity of the LCUs, exposure time, distance from the curing tips, and wavelength of the light absorbed by the sealant material.

The curing light tips were placed in contact with the cusp tip of the tooth during polymerization. This ensured that both light sources were at a relatively constant distance away from the sealant material to be polymerized.

The useful light for polymerization can be determined by measuring the wavelength and intensity of the light. Intensity is measured as milliwatts per square centimeter ( $\text{mW}/\text{cm}^2$ ). If a curing light potentially generates a high-energy output of  $1000 \text{ mW}/\text{cm}^2$  but the wavelength of light does not match that of the absorption spectrum of the photoinitiator, then no useful energy is being utilized. This will be manifested clinically as a failed restoration.

The light emission spectra of the LCUs used in the study were generated in the Dental Materials Laboratory using a Spectrophotometer (Figure 2). This emission spectra shows the relative intensity and wavelength of LED Freelight, Spectrum 800 QTH light as well as the absorbance spectrum of CQ, the photoinitiator present in Clinpro's sealant. The LED light wavelength ranged from 420 nm to 520 nm with a maximum peak emission at 460 nm. The Spectrum 800 QTH Light ranged from 380 nm to 520 nm and peaked at 490 nm. The peak emission of the QTH light was at a slightly longer wavelength than that for LED. The difference was marginal at 460 nm for LED and 490 nm for the QTH LCU. The light emission spectrum of the LCUs was compared with that of a representative absorbance spectrum for CQ. Both emission spectra matched

the absorbance of CQ very well and will therefore polymerize the sealant material containing CQ as a photoinitiator.

According to Uhl et al. CQ's absorption spectrum ranges between 400 nm to 500 nm and peaks at 460 nm.<sup>71</sup> The author indicated that the LED LCU used in that study was more effective than QTH LCU in polymerizing dental composites. Although the emission spectra obtained for both light sources, as generated in the Dental Materials Laboratory, were similar to those seen in Uhl's study, the same conclusion cannot be readily made with the polymerized sealant material.

The clinical data evaluation for QTH Light showed that 97.3 percent, 93.1 percent, and 91.7 percent of the sealants received a score of "A" at baseline, three and six months respectively. The LED LCU on the other hand received a score of 87.7 percent, 86.1, percent and 83.1 percent at baseline, three months and six months evaluation. QTH LCU showed a marginally statistically significant difference in clinical retention compared to the LED LCU at baseline. At the three and six months evaluation there were no statistically significant differences noted in sealant retention for sealant polymerized with either light source.

The clinical examination of the sealants classified them into ordered categories. The cumulative logit function was used to statistically analyze this data by modeling the probability of the outcome falling into the first class versus the outcome falling into the other three categories.

The design of this study resulted in there being two sources of variability. There is variability from measurements taken on different teeth for a subject and variability from measurements taken on different subjects. Because measurements taken on teeth

from the same subject are more similar (i.e. more highly correlated) than measurements taken from different subjects, it is imperative to incorporate this within-subject variability into the model in order to get the most accurate estimate for the standard error of a difference and hence the most reliable statistical comparison of the two treatments.

The wear analysis data were carried out on 31 pairs of sealed teeth of which 22 were premolars, and nine, molars. The other 41 pairs of sealed teeth were not included in the wear analysis, because the initial baseline impressions were not of diagnostic value. During the early data collection phase of this study, a bite-stick was used to make the impression. It was originally thought that the pediatric population would tolerate the bite-stick better than they would a sectional tray for impression, because only the occlusal surface of the teeth was necessary for the wear analysis. The resin material leaked through the porosity of the bite-stick when left standing for a 24-hour period. Re-pours were sometimes necessary, but at other times the quality of the impression rendered it a failure. Sectional trays replaced the bite-sticks during the course of the study to correct this problem.

For wear analysis using the SigmaScan values, mean decreases of sealant area for each tooth were analyzed. A linear model with a single factor for light source was used. It was imperative to incorporate the two sources of variability into the linear model (variability from measurements taken on different teeth for a subject and variability from measurements taken on different subjects) in order to get the best estimate of the standard error of the difference, so that a better statistical comparison of the two treatments could be obtained. To achieve this, a compound symmetry covariance structure was used. The compound symmetry structure assumes that teeth closer together are likely to have more

similar wear patterns than teeth farther apart. Even though this is an over-simplification, it was the best model to fit this smaller dataset and was used instead of a more complex model requiring a much larger dataset.

The standard linear model has two assumptions that need verifying in order to ensure that the statistical comparison of treatment means is valid. These two assumptions are that the random error terms follow a bell-shape curve, i.e. normally distributed, and that the variance of the error terms does not increase with the mean or otherwise systematically differ between the two light sources. After fitting these data to the model, the residuals were evaluated. (The residuals are estimates of the random error terms of the linear model). The residuals did not follow the bell-shaped pattern of a normal distribution. Any statistical comparison of the resulting treatment means would be based upon this assumption of normality and so would not be a reliable comparison.

To correct for this, the log scale was employed. This resulted in residuals that better followed a normal distribution. The resulting checks of the linear model assumptions showed that the two assumptions were upheld, so that a statistical comparison of the treatment means on the log scale was done. The ratios of the mean decreases of sealant area to the baseline mean sealant area was also analyzed (i.e. decrease as a fraction of baseline) using the same linear model listed above. The residual plots did not show violation of assumptions, and so there was no need to transform the ratios to another scale.

Wear analysis of the scanned data indicated that molar teeth showed marginally significant more wear when the LED light source was use (Table XIII) (p-value 0.0755). If the sealant was not cured well with the LED light source, molar teeth would be

expected to show more wear earlier as they are placed in function. No significant difference was noted between light sources for premolar teeth. This could be related to the fact that less occlusal load is placed on premolars than on molars. A longer evaluation time in function may be needed before significant wear is noticed on premolars.

The greatest problem with this study was recruiting and retention of patients. It proved challenging to carry out this study while at the same time managing a regular patient schedule over which the operator had no control. During the course of the study, dedicated auxiliaries were not available. Each placement process required the operator to spend some time training new auxiliary before proceeding with the study. Clinical photographs were taken with a Dental Eye camera, the resulting quality of the photographs were poor.

Recommendations for improvement of this study are:

- 1) Larger sample size for both retention and wear data analysis.
- 2) Long term follow up of sealant placement.
- 3) Use of canned compressed air for drying prior to sealant placement.

SUMMARY AND CONCLUSION

This clinical study investigated the efficacy of 3M Freelight LED LCU and that of the QTH LCU by evaluating retention and wear of the Clinpro's (3M ESPE) sealant material over six months of function. Based on the results of this study the following conclusions can be made:

- 1) After one week in function (baseline values), the QTH light showed marginally significant better retention (p-value 0.05001).
- 2) There were no significant differences between light sources at three-month and six-month follow-up visits.
- 3) Molar sealants showed marginally significant more wear when polymerized with LED LCU (p-value 0.0755).
- 4) Premolar sealants showed no significant difference in wear.

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APPENDIX

## APPENDIX I

## INFORMED CONSENT

Study No: \_\_\_\_\_

## IUPUI AND CLARIAN INFORMED CONSENT STATEMENT FOR

**A Clinical Study of Sealants Polymerized with Two Different Light Sources****Study Purpose:**

You are invited to join a study entitled "A Clinical Study of Sealants Polymerized with Two Different Light Sources" because you have expressed an interest in having sealants placed on your teeth. This study is designed to test the effectiveness of two different lights to harden the plastic coatings placed on top of your teeth. If you agree to participate, you will be one of approximately 35 subjects who will be participating in this study.

**Procedure for the study:**

In this study we will be evaluating the effectiveness of two different light sources, both of which are used by dentists in placing sealants. At the screening examination, we will check to see if you need sealants on your teeth. Should you be selected and agree to participate in this study, five visits will be required. On your first visit sealants will be placed on your teeth and it will be cured with one of the lights used in this study. Before placing the sealant, the dentist will isolate your tooth with a sheet of rubber or cotton rolls to keep it dry. Your tooth will be thoroughly cleaned with a rubber cup and some very fine sand. The fine sand will then be washed off with water and the teeth will be air-dried. A blue gel, will be applied to entire top of the teeth to receive the sealants. After 30 seconds the blue gel will be rinsed off thoroughly. A frosty white appearance of the top of the tooth indicates that your tooth is ready to receive the sealant. If the surface gets spit on it or a frosty white surface is not there, the blue gel will be placed on the tooth again. One randomly (like flipping a coin) selected sealant will be hardened with one kind of light and the one on the other side with another kind of light. The sealants placed on your teeth will be evaluated. The evaluation will consist of taking color slides and an impression of your teeth with a putty-like material. The appointment for the placement of the sealants will take approximately one hour. Your first appointment after sealant placement will be one week later. You will need to return for the same kind of evaluation at 3, 6 and 12 months. These evaluations will involve take color slides and impression of your teeth. All return appointments will take approximately 30 minutes. The expected duration of your participation in this study will be approximately 3 hours over the period of 12 months.

**Risks of participating in the study:**

Your teeth may feel a little different when you bite down after they have sealants on them. If you have a problem, contact Dr. David Avery at (317) 274-9604. There is a risk of infection from instruments, but this is unlikely as all instruments, which are used in the mouth, are either protected with a barrier during use, which is changed between subjects, or sterilized in a special machine and processed at a very high temperature before they are used again. Strict infection control procedures are used such as gowns, masks, gloves and glasses to minimize cross contamination.

1-29-02

\_\_\_\_\_  
Subject's Initials

**Costs of participating in the study:**

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. It is your responsibility to determine the extent of your health care coverage. You are not waiving any legal rights or benefits to which you may be entitled.

**Confidentiality:**

Because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA or IUPUI Institutional Review Board or its designees may choose to inspect records identifying you as a subject in this investigation. Your name will not appear on any of the recording forms. You will be identified by a unique number. Pictures will only contain your identifying number and a number showing how long since you started this study. Your name will not be revealed in any published reports that may be written concerning this study.

**Payment for participation:**

The placement of sealants are being provided at no cost to you. Your parking stubs will be validated. You will receive \$5 at the 3 month evaluation, \$10 at the 6 month evaluation and \$15 at the 12 month evaluation for your participation in the study.

**People to contact:**

If you have questions regarding the study, you can contact Dr. David Avery at (317) 274-9604. In the event of an emergency, you may contact Dr. David Avery at (317) 212-6802. A subject representative who is not associated with this research to whom you may address complaints about this study, as well as about your rights as a research participant, may be reached at (317) 274-8220.

**Subject's Consent:**

I give my consent to participate in this research study. I may drop out of or be withdrawn from the study due to the dentists concern for my oral health, without fear of changing the investigator's interest or the quality of dental care which I may seek or receive in the future from the doctors participating in the study.

I acknowledge receipt of a copy of this informed consent statement.

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or Guardians Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

ABSTRACT

A CLINICAL STUDY OF SEALANTS POLYMERIZED WITH TWO DIFFERENT  
LIGHT SOURCES

by

Marcia Stoddart White  
Indiana University School of Dentistry  
Indianapolis, Indiana

This clinical study investigated the efficacy of the new LED LCU technology when compared to that of the QTH LCU by evaluating retention and wear of Clinpro (3M ESPE) sealant material over six months of function. This study was designed as a split mouth, randomized clinical study. Sealants were placed and polymerized on contralateral teeth of 35 patients, 33 of which successfully completed the study. The sealants were evaluated for clinical retention at baseline, three months, and six months by two evaluators. For the wear analysis, the area of the sealant wear at six months is reported. Nine pairs of molars and 22 pairs of premolar teeth were used. This sample size is smaller than the original sample used for clinical evaluation, because a number of the baseline impressions had to be discarded due to poor impression quality. Subsequent impressions were taken at three months, and six months. Epoxy replicas were made from the impressions and the occlusal surface of each replica was digitized using SigmaScan

software. A cumulative logit model was applied to the clinical data, and a linear model was applied to the wear analysis.

The results for clinical retention over the six months of function were as follows. At Baseline, for the QTH, 97.3 percent of the teeth received an Alpha score; 2.7 percent received a score of B. For the LED, 87.7 percent received a score of A; 12.3 percent received a score of B. At three months follow-up, for the QTH, 93.1 percent received a score of A; 6.9 percent received a score of B. For the LED, 86.1 percent received a score of A; 12.5 percent received a score of B, and 1.14 percent received a score of C. At six months follow-up, for QTH; 91.7 percent received a score of A; 8.3 percent received a score of B. For the LED, 83.3 percent received a score of A; 15.3 percent received a score of B, and 1.14 percent received a score of C.

The hypothesis was that there would be no significant difference in clinical retention and wear of Clinpro's sealant polymerized with the QTH or the LED light sources over six months of function. Based on the results of this clinical study, the following conclusions can be made:

- 1) At baseline, Clinpro's sealant polymerized with QTH light source showed marginally significant better retention than LED light source (p-value 0.05001).
- 2) There was no significant difference between light sources for sealant clinical retention at three-month and six-month follow up visits.
- 3) Wear analysis resulted in marginally significant more wear for molar sealants polymerized with LED LCU (p-value 0.0755).
- 4) Wear analysis showed no significant difference for premolar sealants polymerized with either light source.

CURRICULUM VITAE

Marcia Stoddart White

EDUCATION:

July 1978 to May 1982	University of the West Indies Barbados
August 1990 to August 1992	Florida Atlantic University, West Palm Beach, FL
August 1993 to May 1997	Howard University, College of Dentistry, Washington DC
August 1997 to August 1998	Bureau of Medicine and Surgery, US Navy; AEGD
August 2001 to July 2003	Indiana University, Graduate Pediatric Dentistry.

DENTAL EXPERIENCE (United States Navy):

General Dentist, August 1997 to August 2001  
Camp Foster, Okinawa Japan  
Naval Air Station, Patuxent River Maryland  
Pentagon Tri-service dental clinic, Washington, DC.  
Dahlgren Dental Clinic, Virginia

Pediatric Dentist, July 2003 to present  
Naval Hospital, Camp Lejeune, NC

PROFESSIONAL AFFILIATIONS:

American Dental Association (ADA)  
Academy of General Dentist (AGD)  
Association of Women Dentists (AWDA)  
National Dental Association (NDA)  
American Academy of Pediatric Dentist (AAPD)

PRESENTATIONS/LECTURES:

38<sup>TH</sup> parallel dental society  
Seoul, Korea; March 12 to 15 1998  
Table clinic presentation  
Title: Coping reduction technique