

# ADA Professional Product Review®

A Publication of the Council on Scientific Affairs

## In This Issue:

Unbiased.  
Scientifically Sound.  
Clinically Relevant.  
User-Friendly.

### Letter from the Editor – David C. Sarrett, DMD, MS



I rarely tell anyone, “You really should pay attention to this.” If you place composite restorations daily in your practice, you really should pay attention to what we are presenting in this issue of the PPR. It will be important to understanding how you can be certain your restorations are cured optimally and, what factors affect light-curing technique. We explored these questions last month at the ADA Professional Product Review’s Product Forum (see page 28). Here are some of the comments we heard from the more than 125 participants who took the one-hour hands-on free CE course:

- I was surprised by how much the output of a curing light could degrade without my noticing.
- I did not realize that most curing lights experience a significant

drop in irradiance over very small clinical distances.

- I wasn’t aware that curing lights can deliver a lot of heat very quickly.

And, the comments came from clinicians of all ages—some graduated dental school just this year while others have practiced more than 30 years. Light-curing of composite restorations is a good example of dentistry as an art and a science. **These dentists learned that light-curing is not as simple as they believed.**

For this issue, the ADA Laboratory conducted an evaluation of seven LED curing units. **The bottom line?** An LED curing unit may have a non-uniform irradiance distribution across its light-emitting tip, multiple LED chips with different spectral emission wavelengths or both. This means that the position of the curing unit could have a significant effect on both the radiant power and the wavelength of the light received by the resin-based composite material—both of which could result in suboptimal curing.

Did you know that you can report problems that you’ve had with drugs and other medical products to the FDA? In this issue, we tell you how to do it through MedWatch, the FDA’s gateway for clinically important safety information and for safety alerts and product recalls. Lastly, if you’ve experienced back, shoulder or wrist pain, be sure to read “Ergonomics and Dental Practice: Preventing work-related musculoskeletal problems.” Planning is underway for our 2015 editorial calendar. Do you have a product or product category that you’d like considered for evaluation? Drop me a line at [ppreditor@ada.org](mailto:ppreditor@ada.org)

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# Ergonomics and Dental Practice: Preventing work-related musculoskeletal problems

*Editor's Note: These articles are intended to be an informational resource only. The views expressed are those of the authors and do not necessarily reflect the opinion or policy of the ADA. The article's contents are not a substitute for the dentist's own judgment and dentists are encouraged to consult with other professionals, as and when appropriate, regarding the information herein.*

**P**racticing the art of dentistry requires a high degree of concentration and precision. But awkward postures, repetitious hand movements, and persistent vibration to the hand and wrist from a highspeed handpiece can make practitioners vulnerable to musculoskeletal disorders. Consider that many dentists often find themselves in a static, uncomfortable position when treating patients. This sustained position can lead to pain, injury, or, in severe cases of musculoskeletal disorders, disability or early retirement.

In this article, the ADA Professional Product Review editor Dr. David Sarrett asks physical therapist Tim Caruso and professional ergonomist Tamara James about ways dentists and their team members can prevent work-related musculoskeletal disorders.

## What are some of the most common ergonomic issues/risks that dentists face in clinical practice?

**Tim:** The list is long and includes:

- Poor working postures and positions.
- Sustained muscular contractions during long procedures that can lead to decreased blood flow to tissues, muscle spasms and increased stress on pain-producing structures.
- Significant repetitive movements with forceful exertions during many procedures.
- Visual fatigue due to poor visualization, inadequate lighting of the oral cavity or lack of magnification.
- Poorly working equipment or lack of adjustable equipment.
- Stressed patients<sup>1</sup>: practitioners often share the stress felt by patients.

**Tamara:** Yes, dentists themselves also can be stressed, which increases the risk for a musculoskeletal injury.<sup>1</sup> Increased muscle tension as well as increased fluid pressure—such as from elevated blood pressure—can contribute as much or more than biomechanical risk factors. For example, job stress from a difficult

surgical procedure with little or no rest, in addition to time pressures, adversely impacts the musculoskeletal system. Taking adequate breaks would go far to help mitigate exposure to repetition and forceful exertions, but the demands to keep working typically outweigh the desire to take breaks. Exposure to hand-arm vibration from highspeed handpieces also can be a risk factor for nerve injuries of the hands and wrists.

## Do you see dentists with specific work-related musculoskeletal disorders or injuries?

**Tamara:** Yes, it does seem to be quite common within this profession. Estimates show a dentist can work up to 60,000 hours in a lifetime, often working in awkward and tense postures. It can be devastating for dental health professionals who have to give up working in this field because of musculoskeletal disorders. One study in the United Kingdom found that nearly 30 percent of dentists who retire early cite musculoskeletal disorders as the cause.<sup>2</sup>

**Tim:** It affects the entire dental team—dentists, hygienists and assistants. The dental literature says somewhere between 40 to 60 percent of dental professionals suffer from work-related musculoskeletal issues. In the ADA's Health Screening Program of 2012, 59.8 percent of participating dental hygienists/ chairside assistants and 56.4 percent of participating dentists had musculoskeletal symptoms. Thirty-seven percent were working 15 to 30 years. Thirty percent had symptoms over 10 years. Seventy-nine percent had symptoms that were worsening or unchanging. Forty-four percent believed that their pain was due to repetitive actions during work. Sixty-one percent of the currently practicing dental professionals reported regularly experiencing pain, tingling, or numbness. The most commonly reported symptoms were located in the back (51.0 percent reported) and neck (51.1 percent).<sup>3</sup> Based on my travels, I believe that it may be toward the higher end of that range. I admittedly have a biased audience but upon asking them, I find that it's closer to 85 to 95 percent of those attending.

### Is there predominantly one type of problem that you see more than others? Are there certain types of overuse injuries that are more common than others?

Tim: Back and neck pains tend to be the most frequently reported by the audiences that I speak to, and they are followed by every other area of the body: shoulders, wrists, hand, hip, knees, and ankles. This was supported by our findings at the ADA's Health Screening Program in San Francisco in 2013. Practitioners also commonly experience headaches and "busy brain," or the inability to get restful sleep at night due to replaying the stresses and strains of the day, followed by anticipating the next day's stress—all before getting out of bed to go to work! This also is consistent with what is found in the dental literature.<sup>4-5</sup>

### Are injury patterns different between female and male dentists?

**Tamara:** Most of my work has been with female dentists. They report a variety of areas of musculoskeletal discomfort. Upper extremity (hand and wrist) disorders followed by neck pain seem to be the biggest problems I see.

**Tim:** Females tend to have more upper body complaints while the males have more lower back complaints, and this finding is consistent with the literature. Although, I find complaints can be all over the board when I am questioning attendees at the national dental meetings, primarily at CE classes and presentations.

### What types of dental office equipment might help prevent a practicing dentist's aches and pains?

**Tim:** Equipment that is ergonomically designed and allows the practitioner to lessen the stresses of the practice on their bodies. A good operator stool with an adjustable seat pan, back rest and contoured seating is one option for some. A saddle stool may be a better option for others, while a ball chair or dynamic seat may be the best option for others. Supporting the arms with armrests allows you to unload the stress on the upper body. Having a patient chair that allows easy access to the oral cavity allows for more balanced working posture could be helpful. An example would be a patient chair with a thin, narrow tapered back that allows the dentist to sit in a neutral balanced position with both arms relaxed at the sides. This allows for a neutrally balanced spine with relaxed upper extremities while working.

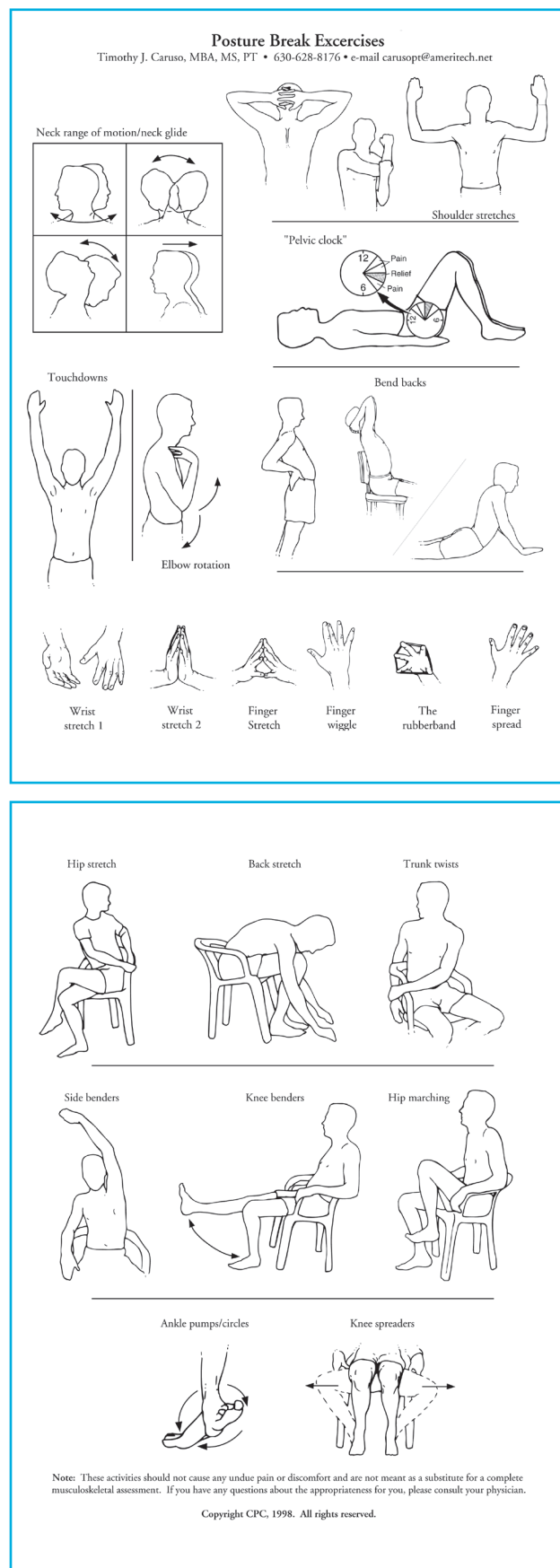


Figure 1. Posture Break Exercises (Reprinted courtesy of Timothy Caruso.)



Figure 2. Quick Stretches for Dental Staff (Reprinted courtesy of the Duke Ergonomics Program, Duke University.)

Neutrally balanced means head over the shoulders, shoulders over the hips and shoulders relaxed at one's sides. Proper magnification and lighting are also assets to the benefit of the practitioner.

**Tamara:** Along with an adjustable chair, loupes and headlamps are some of the best investments a dentist can make to prevent neck problems from developing because they allow for more neutral head and neck postures. Hand instruments should be comfortable, light, and as well-balanced as possible. In other words, when you hold an instrument in your hand you should not feel any muscle tension or pulling.

### Are there any simple things that dentists can do to help avoid these injuries?

**Tim:** Having a good, ergonomically designed operator with equipment that is supportive to the practitioner while allowing them easy access to the oral cavity. This starts with a thin, narrow patient chair to allow the practitioner to get close. And, a supportive operator stool to provide proper spinal alignment and support. Lastly, magnification and lighting that enhance their view into the oral cavity while helping them maintain a balanced spine. Being mindful of your working positions during the course of the day needs to be part of the working equation. Maintaining a good balanced position more times than not during the day is very useful. Add stretching breaks throughout the day between patients or after certain procedures. Listen to those aches and pains from your body and respond to them before they become chronic. (See Figures 1 and 2) Participate in

a regular exercise routine that targets those areas of stress, strain and fatigue. Having all members of the dental team monitoring each other during a working week can go a long way toward positive reinforcement of achieving good working positions while eliminating the poor ones.

**Tamara:** The most important thing is correcting any ergonomic issues in the operator so that the entire team can work in more neutral postures, where the body is aligned and balanced whether seated or standing (see above). For any muscle imbalance that cannot be corrected through ergonomic changes, focus on regular exercise and stay fit to avoid these imbalances. Strengthening the stabilizing muscles, such as those in the shoulders and back, as well as chairside stretching, also can help prevent injury. Also, try to vary your daily routine as much as possible by alternating easy cases with difficult ones as much as possible.

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Tamara James,  
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Ms. Tamara James is the Ergonomics Division Director at Duke University and Health System. The Division is responsible for hazard evaluation and training of over thirty thousand employees involved in every aspect of a medical and teaching institution. Ms. James is a certified professional ergonomist, who received a master's degree in Human Factors

Engineering from George Mason University in Virginia. Ms. James is an assistant clinical professor in Community and Family Medicine and provides ergonomics consultation services that include the direct evaluation of ergonomic hazards, as well as development of training programs, to prevent cumulative trauma disorders related to ergonomic hazards found in various industries.



Timothy J. Caruso,  
PT, MBA, MS

Timothy J. Caruso has been a physical therapist for over 30 years and is a member of the American Dental Association's Dentist Well-being Advisory Committee. He has worked extensively with dental profession since 1988 in ergonomics, injury prevention, productivity, exercise and wellness. His professional expertise focuses in the area of manual therapy

and orthopedics, specifically neuromusculoskeletal disorders. He is a clinical instructor for physical therapy students at Shriner's Hospital and an adjunct faculty member at the University of Illinois at Chicago's Program in Physical Therapy. He is a Certified Ergonomics Assessment Specialist and chairs the Ergonomics Committee at Shriner's Hospital for Children in Chicago.

# The FDA, Medical Recalls and Reporting Adverse Events

“When dentists share their clinical experience via voluntary reporting of Adverse Events, this cumulative experience becomes powerful data that may help uncover unsafe and failed products.” — “Adverse drug and device reactions in the oral cavity.”

*JADA 144(9) September 2013.*

Every year, the U.S. Food and Drug Administration (FDA) receives thousands of complaints and reports from health-care providers, consumers and others through the FDA’s MedWatch program, the safety and surveillance system for drugs and devices in the United States. Safety alerts and recalls include a wide array of products that range from glucose test strips and stents to contaminated drugs used for injection, improper labeling and much more.

You can find a list of medical device recalls and other FDA safety communications at [www.fda.gov](http://www.fda.gov). The FDA also lists an Index to Drug-Specific Information that includes drugs that have been the subject of a Drug Safety Communication, Healthcare Professional Information sheet, Early Communication About an Ongoing Safety Review, and other drug safety communications.

Dental devices and materials occasionally appear on MedWatch. For example, the FDA issued a safety communication in 2012, “Illegal Sale of Potentially Unsafe Hand-held Dental X-Ray Units,” and noted “In order to be legally marketed in the U.S., hand-held dental X-ray units must comply with FDA’s radiation safety and medical device requirements. Manufacturers of these

devices must submit premarket notifications for evaluation by the FDA for safety and effectiveness before the product is cleared for sale in the U.S. Manufacturers of these devices are required to register annually with the FDA in addition to other requirements. The FDA is aware of hand-held dental X-ray units that do not meet these requirements being sold online by manufacturers outside the U.S. and directly shipped to customers in the U.S.”

According to the FDA, a recall is an action taken to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or

when it is both defective and a risk to health. A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. If an implanted device (for example, a pacemaker or an artificial hip) is recalled, it does not always have to be removed. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place.



**Did you know that you can report problems that you’ve had with drugs and other medical products to the FDA? You can do it through MedWatch, the FDA’s gateway for clinically important safety information and for safety alerts and product recalls.**

A recall is either a correction or a removal depending on where the action takes place.

- Correction – Addresses a problem with a medical device in the place where it is used or sold.
- Removal – Addresses a problem with a medical device by removing it from where it is used or sold.

### Who recalls medical devices?

In most cases, a company (manufacturer, distributor, or other responsible party) recalls a medical device on its own (voluntarily). When a company learns that it has a product that violates FDA law, it does two things:

- Recalls the device (through correction or removal)
- Notifies FDA

The FDA monitors reports of adverse events and other problems with medical devices and alerts health professionals, and the public when needed, to ensure proper use of devices and the health and safety of patients. An adverse effect (AE) is any incident in which a medical product was suspected to have resulted in an undesirable experience for the patient. The FDA's Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

### Who Reports to FAERS?

Reporting of adverse events (AE) and medication errors by healthcare professionals and consumers is voluntary in the United States. The FDA receives some adverse event and medication error reports directly from healthcare professionals (such as physicians, dentists, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others). Healthcare professionals and consumers also may report adverse events and/or medication errors to the products' manufacturers. If a manufacturer receives an adverse event report, it is required to send the report to FDA as specified by regulations. Reports that are received directly and those that come from manufacturers are entered into FAERS.

In the article, "Adverse drug and device reactions in the oral cavity," (JADA 144(9) September 2013), the authors state: "Adverse events in the head and neck region often are seen first by dentists and, at times, seen

only by dentists." The researchers document that some of the most commonly prescribed medication cause several adverse events in the oral cavity. They examined the dentist's role in voluntary reporting of drug and device adverse effects and identified the most frequent adverse effects that occur in the oral cavity. They found 6,436 adverse event reports to the head and neck, representing 403 different conditions. Pharyngitis, cough, distorted taste and difficulty swallowing were among the most common adverse effects.

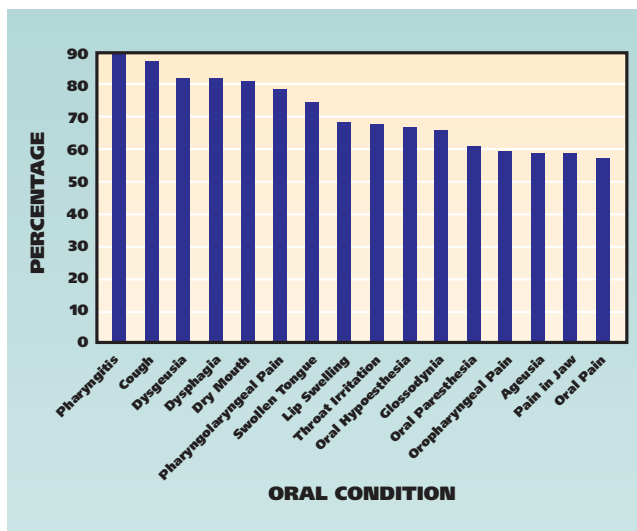


Figure. Most common oral adverse effects for the 100 most prescribed medications in the United States: results from U.S. Food and Drug Administration Adverse Event Reporting System analysis, 2005 through 2010.

Reprinted courtesy of the U.S. Food and Drug Administration

### Voluntary Medical Device Reporting

The FDA encourages healthcare professionals, patients, caregivers and consumers to submit voluntary reports of significant adverse events or product problems with medical products to MedWatch, the FDA's Safety Information and Adverse Event Reporting Program or through the MedWatcher mobile app.

The agency analyzes both voluntary and mandatory reports to develop hypotheses about possible adverse events. In many cases, it's hard to know whether an adverse event that occurs after taking a drug was caused by the medication itself because many adverse events such as stroke or heart attack can result from other causes, such as an underlying illness. But when the adverse event is very uncommon and unanticipated and the event occurs soon after the drug is started, there may be good reason to think the drug caused the adverse event.

Sometimes there is a need to conduct new studies to determine whether or not an adverse event associated with the use of a medical product was in fact caused by that product. The spontaneous reporting system is still the principal mechanism by which signals of such rare, but serious, adverse events are currently detected.

### What to Report to FDA MedWatch:

Health-care providers can use the online MedWatch form to report adverse events that they observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers

**MedWatch** is the FDA's gateway for clinically important safety information and reporting serious problems with human medical products. For more information visit: [www.fda.gov/safety/medwatch/default.htm](http://www.fda.gov/safety/medwatch/default.htm)

U.S. Food and Drug Administration

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- Combination products

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- Cosmetics

For answers to questions about specific products: Call 1-888-INFO-FDA (1-888-463-6332) to speak to an FDA representative



**Behind the Scenes:**

## Touring the ADA Laboratory

The ADA Laboratory is housed in the Division of Science and includes dentists, dental materials specialists, microbiologists, chemists and engineers and a machine shop. Together this group develops and conducts tests and, when necessary, designs the equipment needed to adequately evaluate products, which includes professional products used by dentists and some products in the ADA Seal of Acceptance Program. The Laboratory also designs and applies new tests for the development and revision of standards and conducts research studies on critical and emerging issues of importance to practicing dentists.

*"I encourage members who visit Chicago to stop by the ADA Headquarters and visit the laboratory to learn more about their research capabilities."*

—Dr. David Sarrett, the Review's editor.

To arrange a tour of the ADA, contact Ms. Bridget Baxter at the ADA's toll-free number at 800-621-8099, ext. 2397.

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# An ADA Laboratory Evaluation of Light-Emitting Diode Curing Lights

Light-cured resin-based restorations will function only as the manufacturer intends when they receive the required amount of energy at specific wavelengths. This means that the correct irradiance, exposure duration, and spectral emission must be delivered from the light-curing unit.

For this study, American Dental Association (ADA) Laboratory researchers investigated seven LED curing units. We included the Optilux 501 halogen curing light (Kerr) in all laboratory tests to serve as a point of reference.

We calculated the irradiance values coming from a clinically relevant region of each unit's light beam. We also investigated beam homogeneity, spectral distribution and battery life for each of the curing units, as well as each unit's ability to cure (in terms of depth of cure and degree of conversion) and to cause a temperature rise when curing a polymer-based restorative material—all important factors when purchasing a curing light.

## Irradiance of the Clinically Relevant Region of the Light Beam

Irradiance is a measure of the radiant power striking a specific unit area.<sup>1</sup> For this study, we defined a clinically relevant area over which to measure the radiant power based on the International Organization for Standardization's (ISO) depth-of-cure test found in ISO<sup>2</sup> standard 4049:2009, "Dentistry—Polymer-based restorative materials," and from the dental literature showing that the 4 mm inner diameter mold used for the test approximates a Class 1 restoration.<sup>3</sup>

**Methods.** To obtain irradiance values, we recorded the radiant power (energy per unit per time) striking the surface of a 3.9-millimeter-diameter irradiance probe with the tip of the curing unit centered over the probe and positioned 1, 2, 4, 7 and 9 mm from the probe's surface. The 3.9-millimeter irradiance probe was defined to be a clinically relevant area over which to record the radiant power and was similar to the mold diameter used in ISO standard 4049:2009 mentioned above.

**Table 1. List of Evaluated Products**

Product/ Manufacturer	Power Options	Radi- ometer Included (yes/no)	Cure Time Options (seconds)	Battery Type	Time to Fully Charge	Weight (g)	Price <sup>‡</sup>
Bluephase Style Ivoclar Vivadent	Cordless with corded option	No	10, 15, 20, 30	Li-Po	2 hours	120	\$\$\$
Coltolux LED Coltène Whaledent	Cordless	No	20	Not specified	3 hours	100	\$
Demi Ultra Kerr	Cordless	Yes	5, 10, 20	Ultracapacitor*	40 to 70 seconds	184	\$\$\$
Elipar S10 3M ESPE	Cordless	Yes	5, 10, 15, 20 Continuous (120)	Lithium-ion	1.5 hours	250	\$\$\$
FlashLite Magna 4.0 DentMat Holdings	Cordless	Yes	20	Lithium-ion	Max 5 hours	121	\$\$
SmartLite Max Dentsply	Cordless with corded option	Yes	Standard Ramp Pulse (5,10,15,20) Boost (5)	Lithium-ion	At least 3 hours	220	\$\$\$
Valo Cordless Ultradent	Cordless	No	Standard (5,10,15,20) High (4) Xtra (3)	LiFePO <sub>4</sub> rechargeable batteries	1 to 3 hours	130 without bat- teries, 170 with batteries	\$\$\$\$

The information in this table was derived from product literature.

\*The Demi Ultra uses an ultracapacitor instead of a battery as its power source.

<sup>‡</sup>Price range: <\$500 (\$), \$500–\$1000 (\$\$), \$1000–\$1500 (\$\$\$), >\$1500 (\$\$\$\$)

A cosine corrector attached to an optical fiber behaves as the irradiance probe, which when connected to a spectrometer, allows the measurement of radiation (light) collected by the probe.<sup>4</sup> The system was calibrated using a NIST-traceable light source (HL-3-CAL, Ocean Optics). Three radiant power measurements were taken at each distance for each curing unit, and we calculated the average irradiance by using the area of the 3.9-millimeter-diameter probe. It is important to note that irradiance values were not recorded using the entire tip of the curing unit, but instead, as stated above, we calculated irradiance values received by an irradiance probe at a clinically relevant

region of each unit's light beam. This method provides dentists with information pertaining to how their curing units might perform clinically; however, these irradiance values may not match what the manufacturer reports.

**Results.** Figures 1A and 1B compare the diameter of the irradiance probe used in this study with the ISO standard depth of cure mold.

Figure 2 shows the mean calculated irradiance values received by the irradiance probe at a clinically relevant center portion of each unit's light beam as a function of distance.

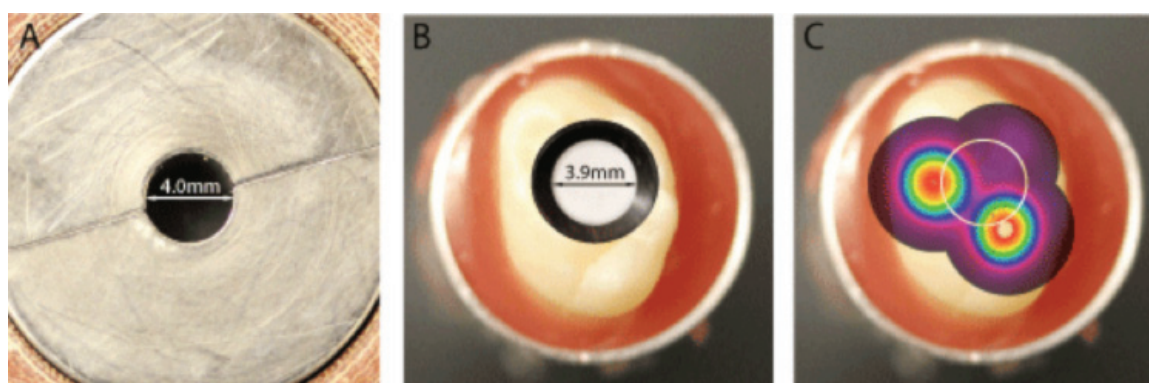


Figure 1. Comparison of diameters of "irradiance probe" and depth of cure mold with a third molar. (A) shows a depth-of-cure mold with its 4 mm inner diameter. (B) shows the 3.9 mm diameter irradiance probe used for the radiant power measurements and superimposed over a third molar. (C) shows the beam profile for the Bluephase Style curing unit superimposed over a third molar; the white circle in the middle represents the irradiance probe (see Figure 3 for description of the beam profile).

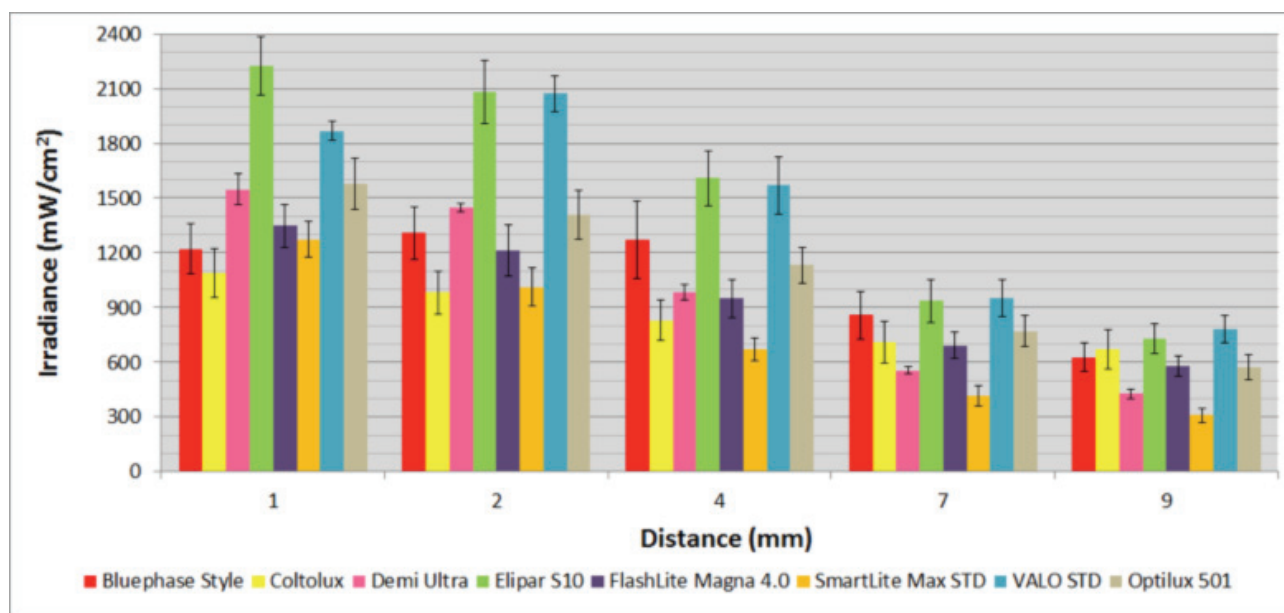


Figure 2. Calculated irradiance values received by a detector at a clinically relevant center portion of each unit's light beam as a function of distance. Each curing unit was tested in standard mode, and the mean irradiation and standard deviation is shown. For each curing unit manufacturer,  $n = 3$  tests per distance.

**Table 2.** Calculated irradiance values received by a detector at a clinically relevant center portion of each unit's light beam at 2 mm and 9 mm distances and percentage decrease in irradiance between the distances.

Curing Unit	Irradiance at 2 mm mW/cm <sup>2</sup>	Irradiance at 9 mm mW/cm <sup>2</sup>	Decrease in Irradiance from 2 mm to 9 mm %
Bluephase Style	1309 (143)	628 (80)	52%
Coltolux LED	981 (117)	672 (108)	32%
Demi Ultra	1449 (23)	428 (26)	70%
Elipar	2081 (174)	729 (80)	65%
FlashLite Magna 4.0	1213 (139)	579 (57)	52%
SmartLite Max STD	1012 (103)	309 (39)	69%
SmartLite Max Ramp	1009 (106)	310 (37)	69%
SmartLite Max Boost	1322 (142)	394 (49)	70%
Valo STD	2071 (99)	782 (76)	62%
Valo High	2855 (130)	1073 (92)	62%
Valo Xtra	4799 (157)	1816 (141)	62%
Optilux 501	1410 (132)	575 (67)	59%
Mean irradiance (n=3) is shown with standard deviation in parenthesis (see Figure 2). For SmartLite Max, the reported modes are Standard (STD), Ramp, and Boost. For Valo, the reported modes are Standard (STD), High power, and Xtra power.			

Table 2 shows calculated irradiance values received by the irradiance probe at a clinically relevant center portion of each unit's light beam at 2 mm and 9 mm distances along with the percentage decrease in irradiance between the distances. It also shows the same information for those curing units equipped with different curing modes.

The dental literature suggests that 400 milliwatts per centimeter squared (mW/cm<sup>2</sup>) be used as a minimum irradiance value for polymerization of light-activated composites.<sup>5</sup> If this criterion is applied, all modes of the SmartLite Max fall below this minimum at 9 mm. Also, the Demi Ultra pulses between two power levels when recording power over time; therefore, we calculated the average power over the collection time and used this to calculate the irradiance values given in Figure 2 and Table 2. You may notice a difference between the irradiance values obtained during our tests and those reported by the manufacturer. Several factors may account for such differences. For example, how the area of the light beam is defined, as noted above, and the distance for which the measurement is made can influence the irradiance values. Note that the values given in Figure 2 and Table 2 are calculated from the total radiant power striking the probe divided by the

area of the probe. Therefore, the irradiance values represent an average irradiance over the entire collection area of the probe. However, for the different LED curing units examined in this study, the irradiance is not uniform across the emitting ends of their light tips, as discussed in the next section.

### Beam Profile

This test quantifies the homogeneity of the beam of light radiated from the curing unit. This was accomplished by using a beam profile system combined with the radiant power measurements obtained in the Irradiance section.

**Methods.** We used the radiant power values combined with a camera-based beam profiler system (BGP-USB-SP620 with a 50-mm lens, [Ophir-Spiricon, North Logan, Utah]) to measure beam

homogeneity, or the distribution of irradiance across the light beam, for each of the curing units at 2 mm and 9 mm from their light-emitting tips. The camera was positioned behind a glass diffuser on an optical table on the other side from the curing units. The distance between the camera and the diffuser remained constant for all measurements, while the emitting tips of the curing units were positioned parallel to the front surface of the diffuser at a distance of 2 mm or 9 mm. With the curing unit activated, the camera focused on the front surface of the glass diffuser. The camera captured the light beam image on the front of the glass diffuser, which was then processed using the data acquisition and analysis software of the beam profiler system (BeamGage Professional 5.11, Ophir-Spiricon).

For each curing unit, using beam profiler software and the average power value collected by the 3.9-mm-diameter irradiance probe, a calibrated irradiance map within the 3.9-mm-diameter region of the image was produced. The map was then applied to the entire beam image to produce the calibrated 2-D and 3-D images of the irradiance distribution of the individual curing unit. (For a more thorough discussion on the use of laser beam profilers for measuring the beam uniformity from dental light curing units, see the Price et al. articles<sup>3, 6-8</sup> in the references below.)

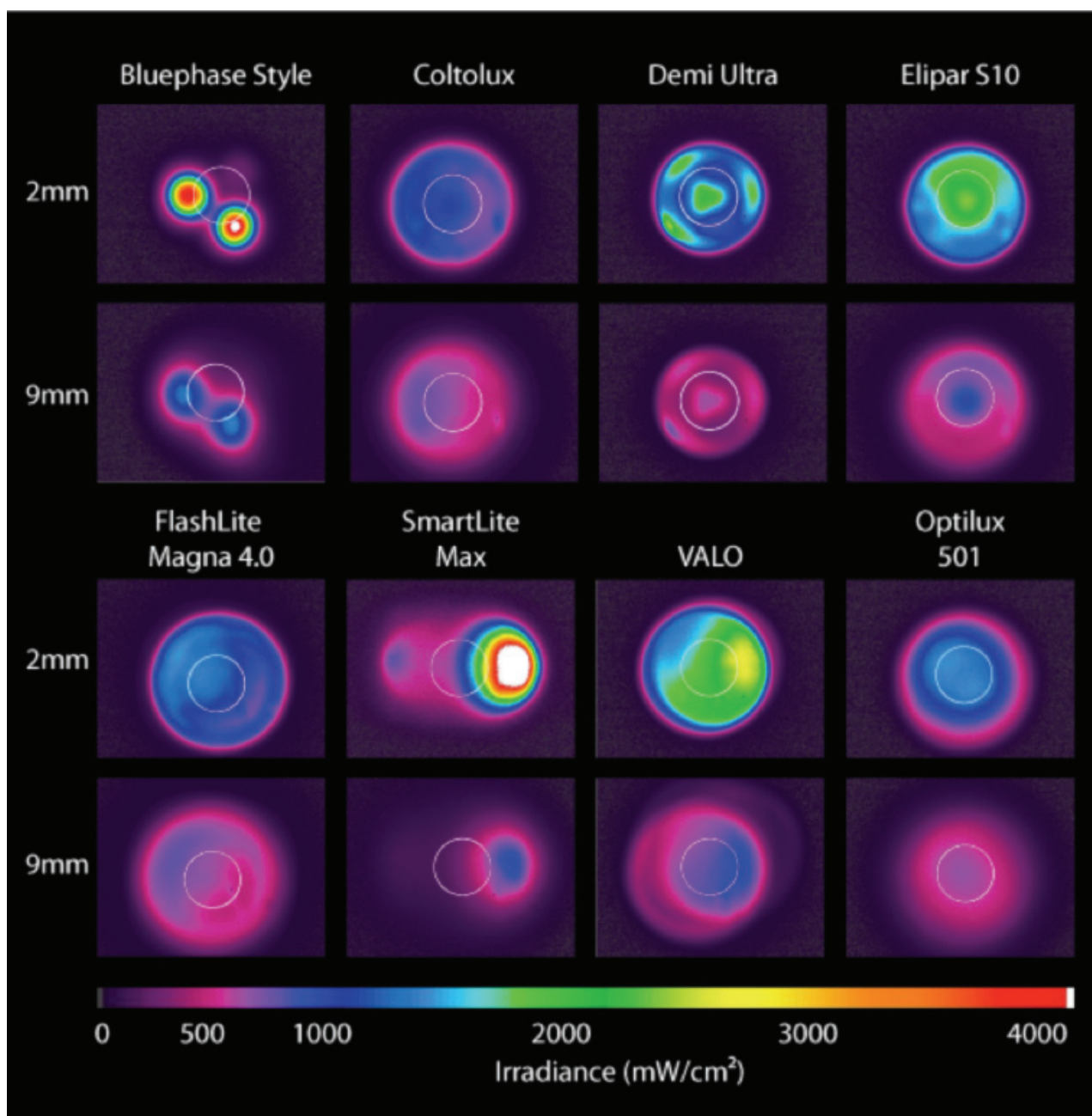


Figure 3. Representative two-dimensional irradiance distribution images of different curing units with the light emitting tip at 2- and 9-mm distances from a glass diffuser. The images all have the same irradiance scale, which is shown at the bottom of the figure. The circle in the center of each image corresponds to the approximate position of the 3.9 mm diameter irradiance probe when the radiant power measurements were obtained, which were used to calibrate the images. The circle in each image also represents the approximate size and position of the depth of cure mold for the depth of cure tests.

**Results.** Figures 3 and 4 show representative 2-D and 3-D images of the calibrated irradiance images for the different curing units at distances of 2 and 9 mm on the same irradiance scale.

It is important to note that irradiance is not homogeneous across the light beams of the different LED curing units. Average irradiance values reported for curing units like those in Figure 2 can make it seem like the radiant power emitted from a curing unit is uniformly distributed across its light beam. However, Figures 3 and

4 clearly show that this is not the case. The color-coded images show that the irradiance distribution varies across the light beam for all of the LED curing units. For example, some profiles, such as the Bluephase Style and the SmartLite Max, range from below  $500 \text{ mW}/\text{cm}^2$  to over  $4000 \text{ mW}/\text{cm}^2$ .

The image for the SmartLite Max curing unit in Figure 3 clearly shows the reason for its poor results in the Irradiance test (see Table 2 and Figure 2).

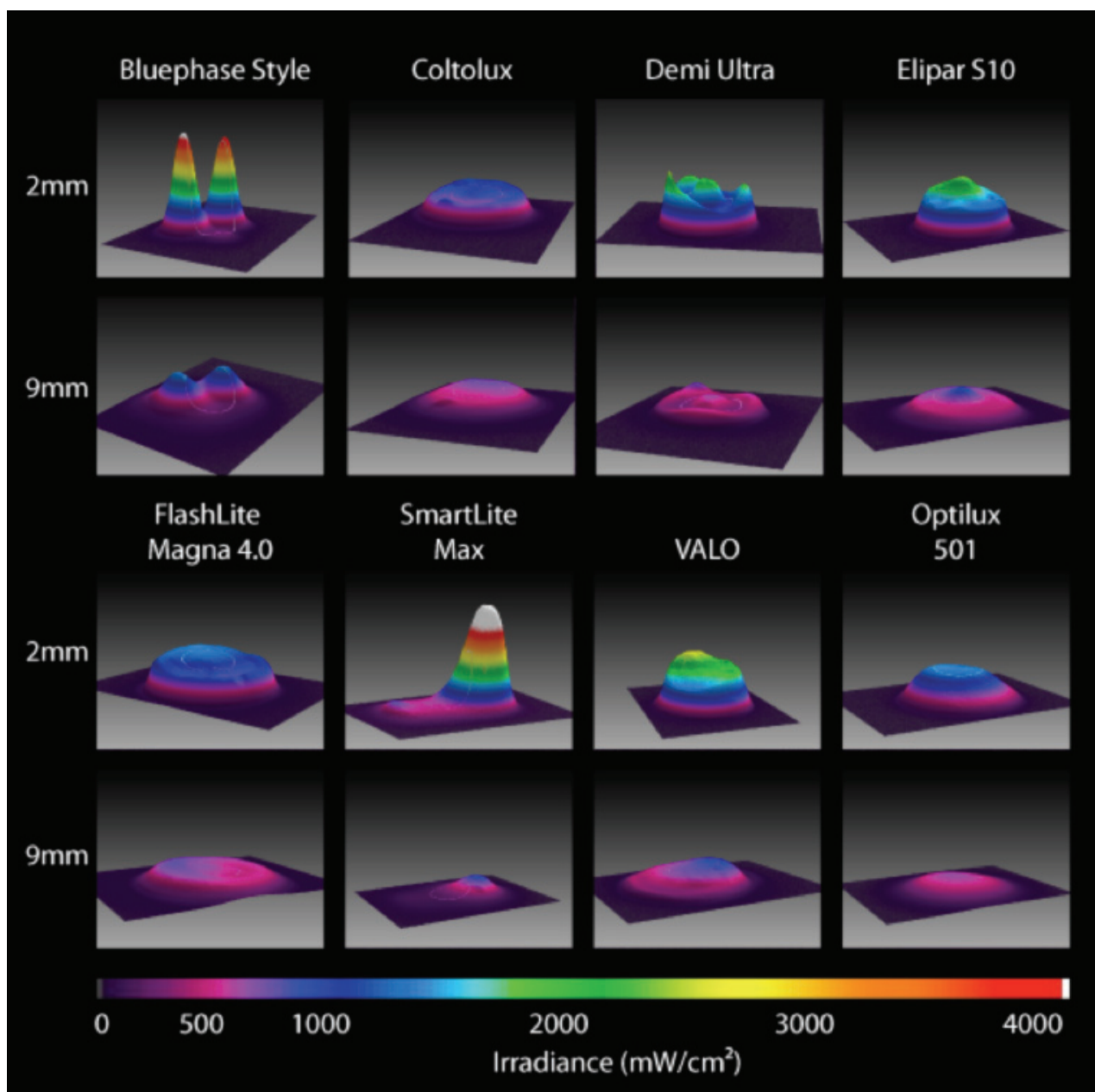


Figure 4. Representative three-dimensional irradiance distribution images of different curing units with the light emitting tip at 2- and 9-mm distances from a glass diffuser. The images all have the same irradiance scale, which is shown at the bottom of the figure. However, the height (z-axis) of the images is not on the same scale for all of the images.

That is, it can be seen that the SmartLite Max has a high irradiance “hot-spot” region on its beam profile; however, when the center of the light-emitting tip of the curing unit is centered over the center of the irradiance probe, almost the entire hot-spot region is outside the collection area of the irradiance probe. As stated in the manufacturer’s instruction booklet,<sup>9</sup> the SmartLite Max “has an arrow embossed on either side of the LED head for alignment with the target.” We used this aligning arrow when centering the curing unit over the irradiance probe. Therefore, we believe that the curing unit was used in a clinically relevant manner, and that practitioners

should consider the location of the high irradiance region of the beam in relation to the size of the restoration being cured when using this curing unit.

Similarly, Figure 3 shows that when the Bluephase Style is centered over the irradiance probe, much of its high irradiance region is also outside the collection area of the probe. Therefore, for both the Bluephase Style and SmartLite Max curing units, movement of the units so that their high irradiance regions are centered over the irradiance probe will produce much higher irradiance values than those reported in Figure 2 and Table 2.

Also, the Bluephase Style profile exhibits two overlapping circles ranging from red to blue and then what appears to be a third low irradiance circle. This is because the Bluephase Style curing unit is comprised of three individual light-emitting diode (LED) chips (two blue and one violet). Likewise, the SmartLite Max profile appears to exhibit two overlapping circles, one high-irradiance and one low-irradiance, which is a result of its two different wavelength LEDs. The different wavelength-emitting LED chips in these curing units result in multiple peaks on their spectral emission plots, as discussed in the next section.

### Spectral Range of Emitted Light (Spectral Distribution)

This test identifies the relative amount of power emitted by the curing unit at each wavelength. This is important because the curing unit must emit a sufficient amount of energy at the proper wavelengths, i.e. wavelengths within the absorption range of the photoinitiator for the material being cured, to sufficiently cure a photo-polymerizable material.

**Methods.** We determined the spectral emission for each curing unit by using an irradiance probe/spectrometer

assembly. The tip of each curing unit was centered over the irradiance probe and radiant power measurements were taken 2 mm from the surface of the diffusing material of the probe, which were used to generate spectral emission curves. We then compared the spectral emission plots of the different curing units with the peak absorption range of camphorquinone. Camphorquinone (CQ) is the most commonly used photoinitiator in dental resin formulations,<sup>10</sup> and the photoinitiator used for Heliomolar HB, which we used for the depth of cure and degree of conversion tests.

**Results.** Figure 5 displays representative spectral emission curves for each of the curing units.

The figure also shows a normalized plot of the absorption spectrum for CQ reproduced from the literature.<sup>11</sup> The spectral emission curves for the different curing units overlap the region representing the peak absorption range of CQ, as defined in Figure 5, to a varying extent. For each curing unit, we calculated the approximate percentage of its spectral emission curve that overlapped the peak absorption range (shaded-yellow region) along with an approximate “effective irradiance” for that range in mW/cm<sup>2</sup> (Table 3).

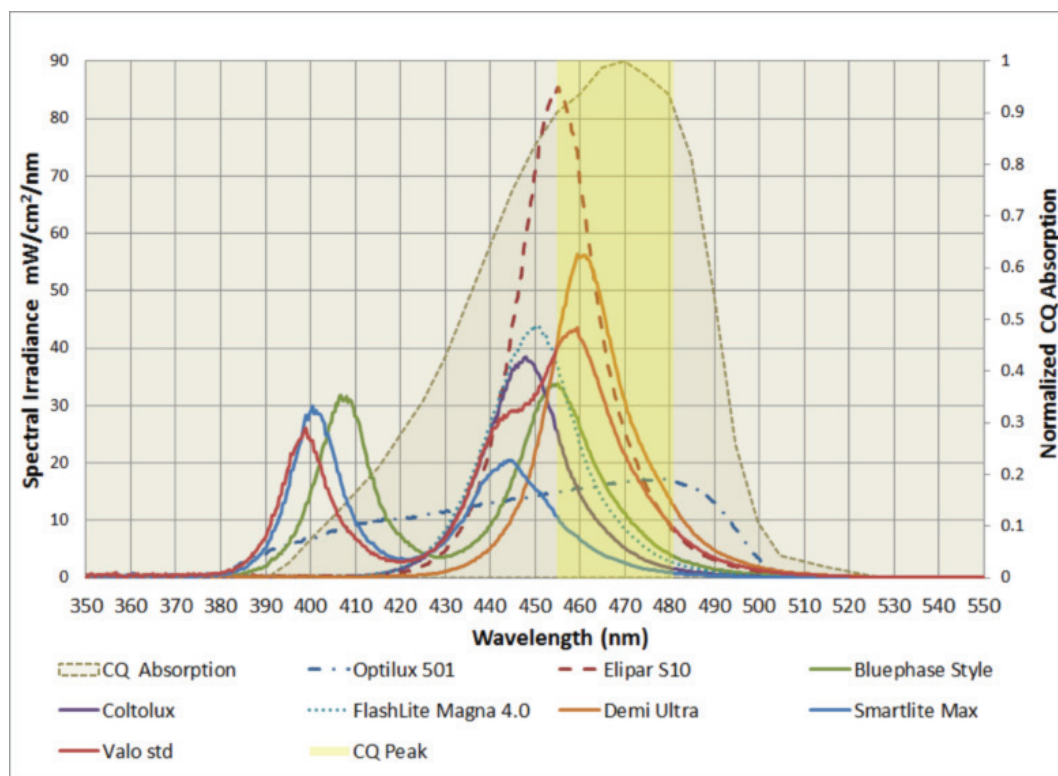


Figure 5. Representative spectral emission curves for each of the different curing units. The normalized absorption spectrum for camphorquinone (CQ) is shown (dotted line)<sup>11</sup>. The shaded-yellow region (455 to 481 nm) represents the peak absorption range for CQ. This is defined as the range of wavelengths in the plot that are included within 10% of the normalized CQ absorption peak of 1.0, which is at a wavelength of approximately 469 nm.

Table 3. Results for peak wavelength, full spectral range, peak absorption percentage, and effective irradiance.

Curing Unit	Manufacturer's Stated Range	ADA Test Results			
		Full Spectral Range (nm)	Peak Wavelength <sup>†</sup> (nm)	Peak Absorption Percentage*	Effective Irradiance <sup>†</sup> (mW/cm <sup>2</sup> )
Bluephase Style	385–515	377–523	455	32%	386
Coltolux LED	450–470	405–512	448	24%	210
Demi Ultra	450–470	410–530	459	68%	898
Elipar S10	430–480	409–523	455	49%	962
Flash Lite Magna 4.0	420–490	403–515	450	30%	333
SmartLite Max (STD)	377–490	372–510	445	10%	96
Valo (STD)	395–480	360–550	459	38%	657
Optilux 501	–	375–507	479	32%	412

\*For each curing unit, this is the percentage of the spectral emission curve that overlapped the peak absorption range (455 to 481 nm) for camphorquinone (CQ), as shown in Figure 5.

†For each curing unit, this is the approximate area of the spectral emission curve that overlapped the peak absorption range for camphorquinone.

\*For the curing units with multiple peaks, the peak wavelength shown is for the one corresponding to the peak absorption range for CQ. Values in the table are from representative spectral emission curves for each of the curing units. STD designates the standard mode was used.

The peak absorption percentage and the “effective irradiance” values provide estimates of the power per unit area that is able to optimally interact with the photoinitiator and were calculated based on the overlapping area of the spectral emission curve with the peak absorption range of camphorquinone. For the defined area of the probe that spectral emission curves were generated from, it can be seen that Demi Ultra (68 percent) and the Elipar S10 (49 percent) have the two highest percentages of their spectral emission curves that overlap the peak absorption range for CQ, with the Demi Ultra having the highest. However, since the intensity of the peak is greater for the Elipar S10, it has a slightly higher “effective irradiance” (962 mW/cm<sup>2</sup>) than the Demi Ultra (898 mW/cm<sup>2</sup>).

For the Bluephase Style, SmartLite Max, and Valo curing units there is a double peak shown in Figure 5. The peak wavelength values provided in Table 3 are for the wavelengths associated with the peak absorption wavelength of camphorquinone (~469 nm). However, the curing units with a second peak centered at around 398 to 408 nm are designed to work with a photoinitiator other than camphorquinone, such as Lucirin TPO that is used in Tetric EvoCeram, for example.

In the Beam Profile section above, we noted that the 2 mm profile of the Bluephase Style exhibits two

overlapping circles going from red to blue, as well as what appears to be a third low irradiance circle, all of which are the result of three separate LED chips (two blue and one violet). Since the white circle in the center of the image (representing the irradiance probe) touches all three circles, the corresponding spectral emission curve exhibits two distinct peaks, one centered at 455 nm and another centered around 408 nm. However, similar to the discussion on irradiance in the Beam Profile section, if the Bluephase Style curing unit is positioned such that one of the red circles (corresponding to a blue LED chip) is positioned directly over the irradiance probe, the peak at 455 nm should get larger (higher irradiance) and the peak around 408 nm should decrease or disappear. This phenomenon is illustrated in Figure 6. It shows the two-dimensional irradiance distribution image for the Bluephase Style along with three different spectral emission curves for the curing unit. In the figure, the circle labeled “3” represents the curing unit positioned with the high irradiance region over the irradiance probe, and it can be seen that the corresponding spectral emission curve labeled “3” shows a single peak centered at 455 nm. Likewise, the circle labeled “1” corresponds to the curing unit positioned over the irradiance probe such that the 455 nm peak mostly disappears, while the 408 nm peak corresponding to the violet LED becomes larger.

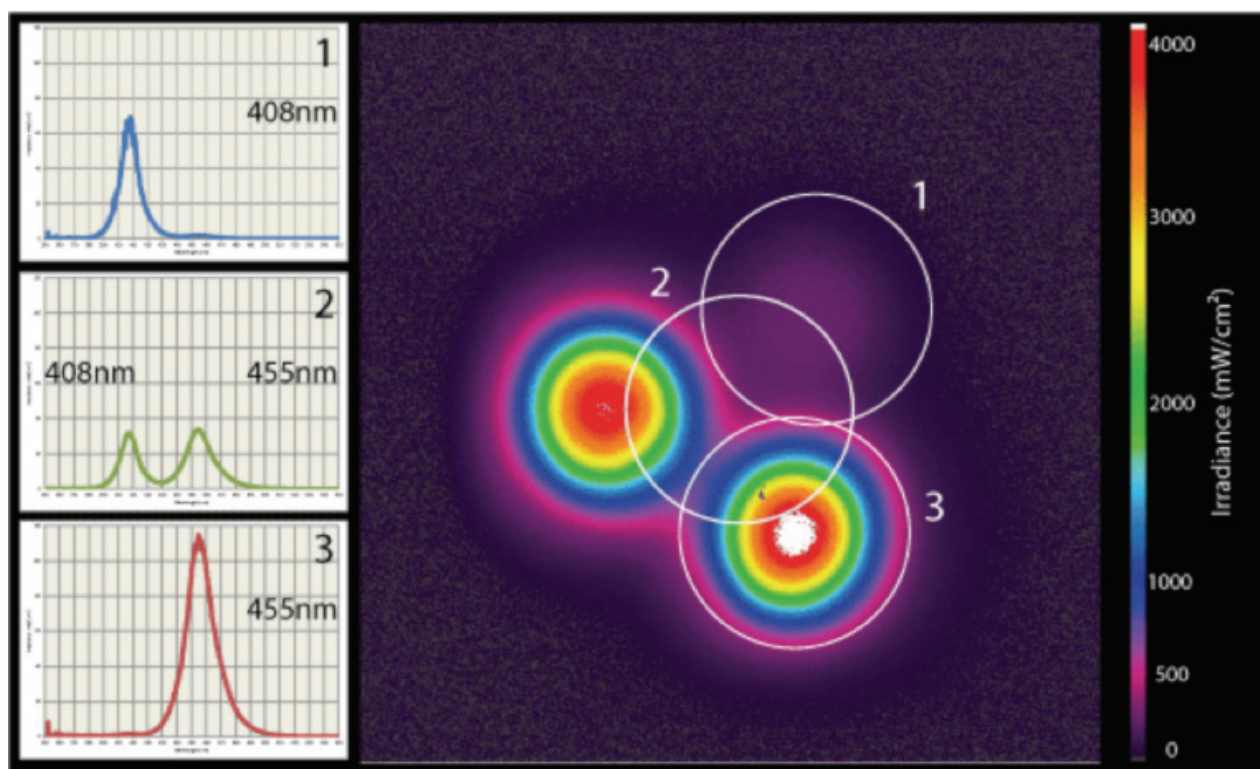


Figure 6. Two-dimensional irradiance distribution image for the Bluephase Style with the light emitting tip 2 mm from a glass diffuser along with three different spectral emission curves. Circles 1, 2, and 3 on the image correspond to the approximate position of the 3.9 mm diameter irradiance probe when the spectral emission curves with the corresponding numbers to the left of the image were generated. Note that circle 2 corresponds to the position of the 3.9 mm diameter irradiance probe when the radiant power measurements were obtained that were used to calibrate the image (i.e., circles 1 and 3 are only associated with the correspondingly numbered spectral emission curves and not the color coded irradiance scale to the right of the image).

Similar experiments were performed with the Valo and SmartLite Max curing units. We found that the Valo has four individual LED chips at its curing tip end corresponding to spectral emission peaks centered at approximately the following wavelengths: 459 nm (two LEDs), 443 nm, and 398 nm. Like the Bluephase Style, the Valo could be positioned over the irradiance probe, such that the spectral distribution curves exhibited only a single peak corresponding to the emission wavelength of the LED chip. As noted above, the 2 mm SmartLite Max beam profile image in Figure 3 appears to exhibit two overlapping circles, one high-irradiance and one low-irradiance. Testing showed that if the curing unit is positioned such that the “hot-spot” in the image is moved over the irradiance probe, the peak centered around 445 increases while the peak centered at about 400 nm decreases, but does not disappear. Conversely, if the curing unit is positioned over the low-irradiance region in the image, the peak centered at about 400 nm increases while the one at 445 decreases, but does not disappear.

This means that it is possible that the curing unit’s

position can have a significant effect on both the radiant power and the wavelength of the light received by the resin-based composite material, which could result in suboptimal curing. For example, if a clinician is placing a Class 1 restoration with a diameter of about 4 mm using a material with CQ as the photoinitiator, it is possible that the Bluephase Style curing unit can be positioned such that circle “1” in Figure 6 corresponds with the area of the restoration.

This would mean that the energy that the material receives will not be at the proper wavelength to optimally interact with the CQ photoinitiator and could result in suboptimal curing of the material. (Note that even under the described conditions, some of the light energy from the “hot-spot” region will be dispersed through the tooth structure and will interact with the material.) This phenomenon can be seen in the following sections on depth of cure and monomer conversion, where some of the results show that the material was suboptimally cured because the high-irradiance regions of the respective curing units were not positioned over the center of the molds.

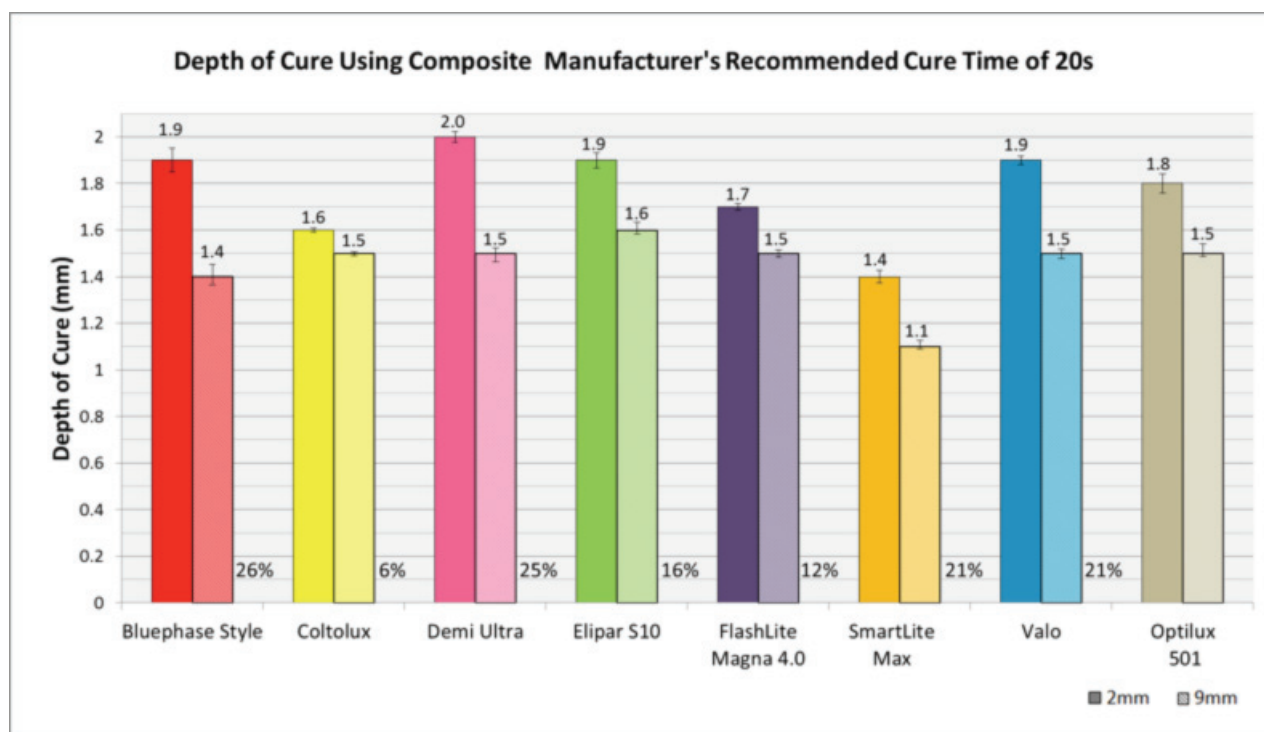


Figure 7. Depth of Cure for Heliomolar HB when using the composite manufacturer's recommended cure time of 20 seconds with the curing tip 2 mm and 9 mm from the sample. Mean depth of cure and standard deviation is shown. For each curing unit manufacturer, n=3 tests per distance. For each LED curing unit, the percentage to the bottom right of the 9 mm bar is the percentage decrease in depth of cure between the 2 mm and 9 mm distances.

## Depth of Cure

This method is based on the depth-of-cure test in ISO standard 4049:2009, "Dentistry – Polymer-based Restorative Materials."<sup>2</sup> The test measures the depth to which a cylinder of polymer-based restorative material is cured once irradiated for a specific curing time. According to the standard, a depth-of-cure measurement at or above 1.5 mm is acceptable. We performed this test using the curing units at different curing times and distances.

**Methods.** To measure depth of cure, we used Heliomolar HB (A2 shade), a microfill composite material that uses camphorquinone as the photoinitiator. We conducted the tests with the curing unit tip placed at distances of 2 and 9 mm from the surface of the composite material, which represented best case (easily accessed area) and worst case (not easily accessed area) scenarios, respectively.

We also used different curing times; the time suggested by the composite material manufacturer, as well as the time suggested by the curing unit manufacturer. First, we tested each curing unit using the 20-second cure time recommend for Heliomolar HB<sup>12</sup> at both 2 mm and 9 mm distances.

Next, we followed specific instructions in the product manuals with respect to curing times and curing modes. For example, two of the curing units have multiple curing modes: SmartLite Max (Standard, Ramp, Pulse, and Boost) and Valo (Standard, High, and Xtra). For the SmartLite Max, the "Operation" section of the manual<sup>8</sup> states to "Always use the settings recommended by the manufacturer of the dental material when selecting the settings for the SmartLite Max Light". Therefore, we used the 20 second cure time recommended by the manufacturer of Heliomolar HB<sup>12</sup> for each of the modes except for the Boost mode, which is programmed to run only at 5 second intervals. For the Valo, specific instructions<sup>13</sup> were given for each of the three modes and for "per layer" and "final cure". In their online literature,<sup>14</sup> Coltux LED claims that it cures "2 mm in only 10 seconds", which was also tested. Besides the statement to "always follow the recommend curing times published by the manufacturer of your dental restorative material", the Demi Ultra manual<sup>15</sup> contains a table with a curing time of 5 seconds for "Universal composite shades A3 and lighter (2 mm depth)"; therefore, we performed testing with a curing time of 5 seconds.

**Table 4.** Depth of Cure for Heliomolar HB based on the curing unit manufacturers' recommended cure times with the curing tip 2 mm and 9 mm from the sample.

Curing Unit / Mode	Curing Time (s)	Depth of cure (mm)	
		2 mm	9 mm
Bluephase Style			
Heliomolar HB	20	1.9 (0.05)	1.4 (0.04)
Product recommendation	15 (2 mm) 30 (9 mm)	1.7 (0.05)	1.6 (0.04)
Heliomolar HB with Anti-glare	20	1.7 (0.03)	1.1 (0.03)
Product recommenda-tion with Anti-glare	15 (2 mm) 30 (9 mm)	1.6 (0.02)	1.3 (0.02)
Coltolux LED			
Heliomolar HB	20	1.6 (0.01)	1.5 (0.01)
Product recommendation	10	1.4 (0.01)	1.3 (0.01)
Demi Ultra			
Heliomolar HB	20	2.0 (0.02)	1.5 (0.04)
Product recommendation	5	1.5 (0.02)	1.0 (0.06)
Elipar S10			
Heliomolar HB	20	1.9 (0.03)	1.6 (0.02)
Product recommendation	10	1.7 (0.06)	1.4 (0.01)
FlashLite Magna 4.0			
Heliomolar HB	20	1.7 (0.01)	1.5 (0.02)
SmartLite Max			
Heliomolar HB / Standard	20	1.4 (0.03)	1.1 (0.01)
Heliomolar HB / Ramp	20	1.4 (0.03)	1.0 (0.02)
Heliomolar HB / Pulse	20	1.2 (0.04)	0.9 (0.01)
Product recommenda-tion / Boost	5 (2 mm) 10 (9 mm)	1.0 (0.01)	0.9 (0.02)
Valo			
Heliomolar HB / Standard / Final layer	20	1.9 (0.02)	1.5 (0.02)
Standard / Per layer	10	1.6 (0.03)	1.3 (0.01)
High Power / Final layer	12 (3x4s)	1.8 (0.04)	1.5 (0.01)
High Power / Per layer	8 (2x4s)	1.7 (0.02)	1.3 (0.03)
Xtra Power / Final layer	6 (2x3s)	1.8 (0.03)	1.4 (0.02)
Xtra Power / Per layer	3	1.5 (0.04)	1.1 (0.02)
Optilux 501	20	1.8 (0.04)	1.5 (0.01)

Mean depth of cure and standard deviation is shown (n = 3 tests per curing time). Data highlighted in red do not meet the ISO standard of at least 1.5 mm depth of cure. The 20-second cure times are based on the composite (Heliomolar HB) manufacturer's recommended cure time.

The Elipar S10 manual<sup>16</sup> states that "Due to the high light output of the Elipar S10 ... the normal exposure times for conventional units can be cut in half without compromising polymerization performance." Therefore, besides the manufacturer's recommended curing time of 20 seconds recommended for Heliomolar HB, a curing time of 10 seconds was also tested. In the manual for Bluephase Style,<sup>17</sup> a curing time of 15 seconds was specified for Heliomolar HB. Additionally, the Bluephase Style curing unit comes with an anti-glare cone; therefore, we performed tests with and without the cone. The manual also stated that "increasing the distance between the light source and the material will require the curing time to be extended accordingly" and, for an example, stated that at 9 mm "the recommended curing time has to be doubled". Therefore, for Bluephase Style at 9 mm, we doubled the recommended curing time of 15 seconds. For the FlashLite Magna 4.0, the instruction manual<sup>18</sup> states to "review manufacturer product instructions for recommended cure times," so we used the 20-second cure time recommended by the manufacturer of Heliomolar HB. For each curing unit, at each distance (2 mm and 9 mm) and curing time, three tests were performed, and the average depth of cure was calculated along with the standard deviation.

**Results.** Figure 7 and Table 4 show the performance of the curing units in the depth of cure tests.

Figure 7 shows the depth of cure results at 2 mm and 9 mm distances when all of the curing units were tested with the same curing time of 20 seconds, which is the curing time recommended by the manufacturer of Heliomolar HB. At 2 mm, with the exception of the SmartLite Max, all of the curing units cured the composite to an average depth greater than 1.5 mm, which is the ISO requirement for this test.<sup>2</sup> However, as the distance increased to 9 mm, the average depth of cure dropped for all of the curing units. The relative drop in depth of cure ranged from approximately 6 percent for the Cotolux to about 26 percent for the Bluephase Style (see discussion below). And, the average curing depths for both the Bluephase Style and the SmartLite Max were both below 1.5 mm.

As noted above, many of the manufacturers have specific curing time instructions in their manuals.

Table 4 shows the depth of cure results at 2 mm and 9 mm for the different curing times and/or modes specified by the curing unit manufacturers, along with the respective depth of cure results for the 20-second cure time recommended by the composite manufacturer. It is important to note that when the distance between the curing unit and the material is increased to 9 mm many of the average depth of cure values fall below the 1.5 mm ISO requirement, highlighted in red in Table 4. Furthermore, at 9 mm, when a curing time recommended by the curing unit manufacturer was less than the 20-second cure time recommended for Heliomolar HB, it resulted in an average depth of cure that was less than the 1.5 mm ISO requirement in all cases except for Valo in the “High” mode with the “final layer” instructions. When comparing depth-of-cure data at 2 mm and 9 mm distances for the Bluephase Style without the anti-glare cone, note that when the manufacturer’s instructions are followed (at 9 mm “the recommended curing time has to be doubled”), the percentage decrease in depth of cure from 2 mm (1.7 mm after 15 seconds of curing) to 9 mm (1.6 mm after 30 seconds of curing) was only about 6 percent, and the depth of cure was greater than the 1.5 mm ISO requirement. This example points to the importance of increasing the cure time with increasing distance from the surface of the composite.

The unsatisfactory results for some of the curing units may be explained by the irradiance distribution images in Figure 3 and the spectral distribution curves in Figure 5. For example, the 2 mm image of the SmartLite Max in Figure 3 clearly shows that the “hot-spot” region is outside the area of the white circle, which approximately corresponds to the position and diameter of the depth of cure mold for the depth of cure tests. And, at 2 mm with a cure time of 20 seconds, the SmartLite Max was the only curing unit not to meet the 1.5 mm ISO requirement for depth of cure. On the other hand, Figure 3 shows that at 2 mm the high-irradiance region for the Demi Ultra approximately corresponds to the area of the depth of cure mold. Furthermore, the peak absorption percentage value in Table 3 shows that a large region of its spectral emission curve interacts with the peak absorption range for CQ, which is the photoinitiator in Heliomolar HB. Thus, at 2 mm with a cure time of 20 seconds, the Demi Ultra showed the highest depth of cure.

## Degree of Conversion

The degree-of-conversion test determined the degree of monomer conversion of a polymer-based restorative material by means of Fourier transform infrared (FTIR) spectroscopy analysis.

**Methods.** Heliomolar HB (A2 shade, Ivoclar Vivadent) was the polymer-based restorative material used for both the depth-of cure-and degree-of-conversion tests, and both tests were conducted with the curing light tip at distances of 2 and 9 mm from the surface of the composite material at different curing times. The degree of monomer conversion of the composite was determined using Fourier transform infrared (FTIR) analysis. Uncured composite material was placed in a Teflon mold, 6 mm in diameter and 2 mm in height. The mold was centered over a diamond horizontal attenuated total reflectance (HATR) crystal on the FTIR spectrometer (Thermo Scientific, Nicolet iS10 FTIR Spectrometer). The infrared spectra were collected using the following settings: 4000–400  $\text{cm}^{-1}$  wavelength range, 2  $\text{cm}^{-1}$  resolution, and 32 scans. From a spectrum, the concentration of available carbon-carbon double bonds (C=C) can be determined.<sup>19</sup>

After the spectrum for the uncured sample was collected, the curing unit to be tested was centered 2 mm above the sample and the sample was cured for the appropriate time, as described in the Depth of Cure section. Five minutes after the end of curing, a spectrum of the cured sample was collected.

From the FTIR spectra, the percent of unreacted double bonds remaining after curing was calculated. The degree of conversion (DC) is obtained by subtracting the percent of unreacted carbon-carbon double bonds from 100 percent.

For each curing unit, at each distance (2 mm and 9 mm) and curing time, five tests were performed, and the average degree of conversion was calculated along with the standard deviation.

**Results.** To put the LED curing unit degree of conversion values in perspective, Figure 8 shows the degree of monomer conversion for Heliomolar HB plotted versus curing time, when cured with the Optilux 501 tungsten halogen curing unit with the tip 2 mm from the surface of the material.

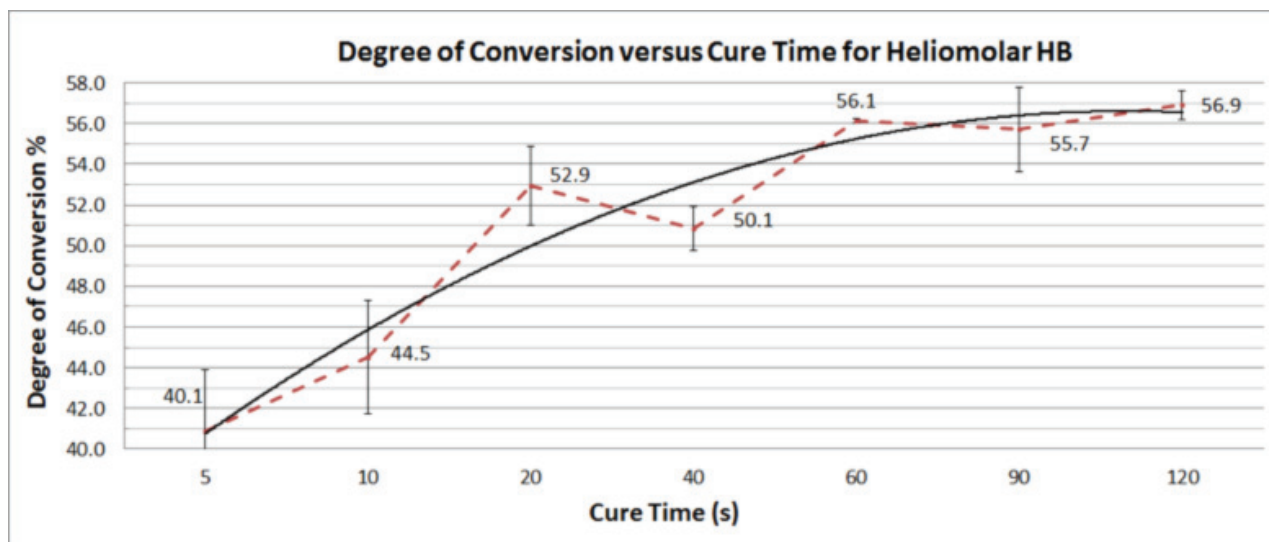


Figure 8. Degree of Conversion versus Cure Time for Heliomolar HB when using the Optilux 501 curing unit with the curing tip 2 mm from the sample. For each cure time, mean degree of conversion (n=3) and standard deviation is shown. The solid line is the plot of a second order polynomial function fit to the data. The  $R^2$  value for the fit is 0.93.

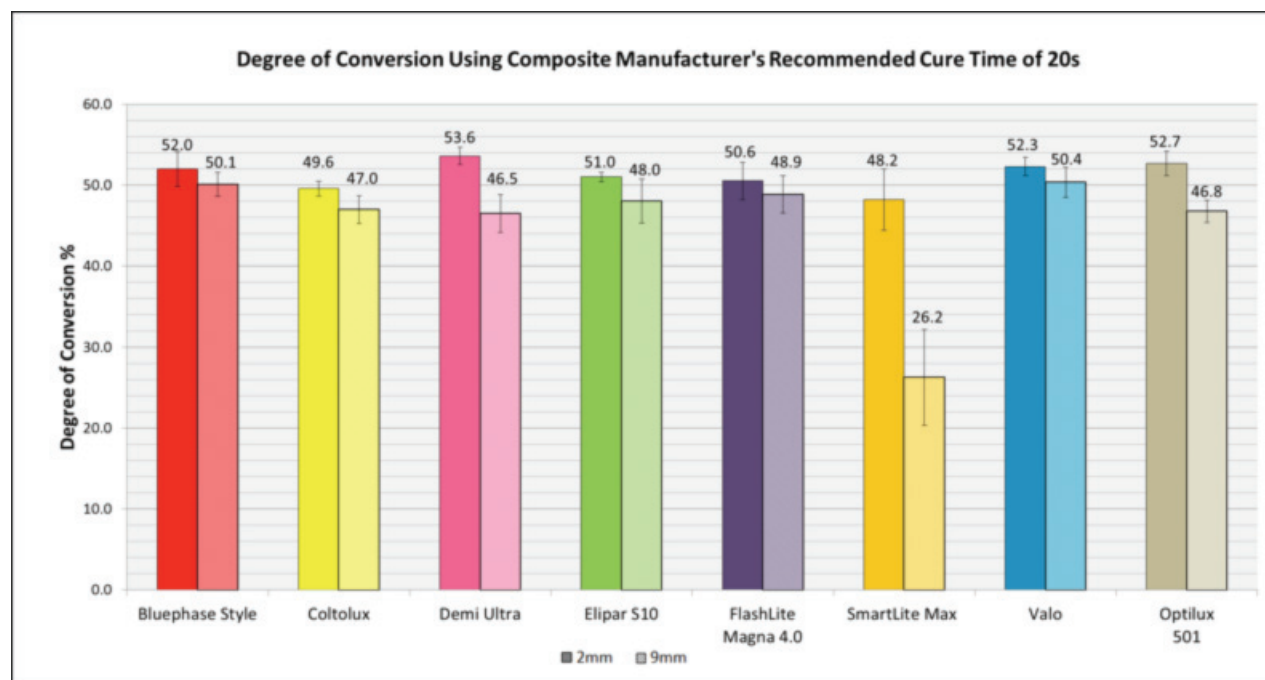


Figure 9. Degree of Conversion for Heliomolar HB when using the composite manufacturer's recommended cure time of 20 seconds with the curing tip 2 mm and 9 mm from the sample. Mean degree of conversion and standard deviation is shown. For each curing unit manufacturer, n=5 tests per distance.

From the figure, it can be seen that for the particular parameters of this study (i.e., specimen thickness, room temperature curing with a tungsten halogen light and measuring conversion 5 minutes after curing), the degree of monomer conversion for Heliomolar HB maxes out at about 57 percent. That is, for the composite and experimental parameters used here, the maximum possible degree of conversion of an individual LED curing unit is approximately 57 percent.

Figure 9 and Table 5 show the performance of the curing units in the degree of conversion tests. Figure 9 shows the degree of conversion results at 2 and 9 mm distances when all of the curing units were tested with the same 20 second curing time recommended by the manufacturer of Heliomolar HB. Similar to the depth of cure results in Figure 7, as the distance increased from 2 mm to 9 mm, the average degree of conversion dropped for all of the curing units.

**Table 5.** Degree of Conversion for Heliomolar HB when using the curing unit manufacturers' recommended cure times with the curing tip 2 mm and 9 mm from the sample.

Curing Unit / Mode	Curing Time (s)	Degree of Conversion (%)	
		2 mm	9 mm
<b>Bluephase Style</b>			
Heliomolar HB	20	52.0 (2.1)	50.1 (2.4)
Product recommendation	15 (2 mm) 30 (9 mm)	49.8 (2.3)	50.6 (2.4)
Heliomolar HB with Anti-glare	20	47.4 (2.0)	44.9 (1.7)
Product recommendation with Anti-glare	15 (2 mm) 30 (9 mm)	47.1 (1.2)	45.5 (6.6)
<b>Coltolux LED</b>			
Heliomolar HB	20	49.6 (0.9)	47.0 (1.7)
<b>Demi Ultra</b>			
Heliomolar HB	20	53.6 (1.1)	46.5 (2.3)
Product recommendation	5	45.9 (2.4)	40.8 (2.4)
<b>Elipar S10</b>			
Heliomolar HB	20	51.0 (0.6)	48.0 (2.7)
Product recommendation	10	48.2 (1.4)	43.3 (1.0)
<b>FlashLite Magna 4.0</b>			
Heliomolar HB	20	50.5 (2.3)	48.9 (2.3)
<b>SmartLite Max</b>			
Heliomolar HB / Standard	20	48.2 (3.8)	26.2 (5.9)
Heliomolar HB / Ramp	20	44.7 (1.6)	31.5 (6.0)
Heliomolar HB / Pulse	20	39.5 (3.4)	ND
Product recommendation / Boost	5 (2 mm) 10 (9 mm)	26.4 (6.3)	ND
<b>Valo</b>			
Heliomolar HB / Standard / Final layer	20	52.3 (1.1)	50.4 (1.8)
Standard / Per layer	10	48.9 (1.0)	39.8 (2.6)
High Power / Final layer	12 (3x4s)	49.2 (1.4)	46.6 (1.6)
High Power / Per layer	8 (2x4s)	45.8 (2.5)	52.3 (1.1)
Xtra Power / Final layer	6 (2x3s)	49.4 (2.9)	41.4 (2.3)
Xtra Power / Per layer	3	44.5 (2.3)	33.4 (2.0)
<b>Optilux 501</b>	20	52.7 (1.5)	46.8 (1.4)

Mean degree of conversion and standard deviation is shown (n = 5 tests per curing time). The 20 seconds cure times are based on the composite (Heliomolar HB) manufacturer's recommended cure time. ND = not determined.

**Table 6.** Degree of Conversion at 2 mm Ranked from Highest to Lowest with Corresponding Depth of Cure Values at 2 mm.

Curing Unit	Degree of Conversion %	Depth of Cure mm
Demi Ultra	53.6 (1.1)	2.0 (0.02)
Valo	52.3 (1.1)	1.9 (0.02)
Bluephase Style	52.0 (2.1)	1.9 (0.05)
Elipar S10	51.0 (0.6)	1.9 (0.03)
FlashLite Magna 4.0	50.6 (2.3)	1.7 (0.01)
Coltolux LED	49.6 (0.9)	1.6 (0.01)
SmartLite Max	48.2 (3.8)	1.4 (0.03)

The 20 second cure time recommended by the manufacturer of Heliomolar HB was used for all tests shown in the table. For Degree of Conversion, mean degree of conversion (n=5) is shown with standard deviation in parenthesis (see Figure 9). For Depth of Cure, mean depth of cure (n=3) is shown with standard deviation in parenthesis (see Figure 7).

Table 6 provides the degree of conversion values at 2 mm (Figure 9) ranked from highest to lowest along with the corresponding depth of cure values at 2 mm (Figure 7) with a 20-second cure time used for all the tests.

It can be seen that the rankings from highest to lowest are consistent for both degree of conversion and depth of cure, with degree of conversion being more discriminating since three of the curing units have the same depth of cure.

### Temperature Rise

We measured the temperature rise caused by a curing light when curing a photo-polymerizable composite material; this includes both the heat generated by the light as well as the heat generated by the polymerization reaction (this also applies clinically). Although the specimen molds used in these experiments do not match the thermal properties of tooth structure, the use of a standard test set-up, as described below, does provide relative comparisons among curing units with respect to the amount of heat generated through a standardized volume of the same material and lot.

**Methods.** For the tests, a mold was created by placing a polyethylene tube on a delrin block with a thermocouple inserted through its base. The resulting mold was 4 mm in diameter and 3 mm deep with the thermocouple protruding 1 mm from the base of the block (2 mm from the top of the mold).

**Table 7. Battery Life for One Full Charge of Curing Units as Evaluated in ADA Laboratories and Stated by Manufacturer.**

Curing Unit	Manufacturer Stated Battery Life for One Full Charge	ADA Tested Number of 30 second on-off cycles in Standard Mode*	ADA Tested Battery Life for One Full Charge in Cure Time†	Manufacturer Stated Recharge Time
Bluephase Style	Approximately 20 min. of cure time	10 seconds 157 times	26 minutes	2 hours
Coltolux LED	Not provided	10 seconds 984 times	164 minutes	Approximately 3 hours
Demi Ultra‡	10 seconds 25 times	10 seconds 25 times	4 minutes	40 to 70 seconds
Elipar S10	10 seconds 360 times (60 min. of cure time)	10 seconds 675 times	112 minutes	1.5 hours
FlashLite Magna 4.0	Approximately 120 min. of cure time	10 seconds 667 times	111 minutes	Maximum of 5 hours
SmartLite Max	10 seconds over 200 times (Standard Mode)	10 seconds 420 times	70 minutes	At least 3 hours
Valo	Not provided	10 seconds 373 times	62 minutes	1 to 3 hours

\*Seconds given indicate the time interval for which the lights were "on" during "on/off" cycles of the test. Each cycle is 10 seconds with the light "on" and 20 seconds with the light "off".

†Calculated by multiplying the number of times the curing unit was able to complete a curing cycle by the 10 seconds the curing light was "on" and then converted and rounded down to the nearest minute.

‡The Demi Ultra does not have a battery as its power source. Instead, it has an ultracapacitor.

The mold was filled with Heliomolar HB and then cured with the tip of the curing unit placed directly on top of the composite. For all of the curing units, a curing time of 20 seconds was used, which is the manufacturer's recommended cure time for Heliomolar HB. The tests were performed in a temperature/humidity chamber with the temperature set at  $36 \pm 1^\circ\text{C}$  and the relative humidity  $50 \pm 5$  percent. The temperature rise was measured by subtracting the starting temperature of the composite after insertion into the mold from the peak temperature reached during curing. The tests were performed with the curing units positioned 2 and 9 mm from top of the mold. For each curing unit, three tests were performed at each distance.

**Results.** When used for 20 seconds, the temperature rise caused by the curing units as they cured the Heliomolar ranged from  $12.9^\circ\text{C}$  (Elipar S10) to  $9.8^\circ\text{C}$  (Coltolux LED) with the curing units 2 mm away from the surface of the composite material and from  $9.4^\circ\text{C}$  (Valo) to  $7.0^\circ\text{C}$  (SmartLite Max) with the curing units 9 mm away, as shown in Figure 10. Since the molds used in this study are not representative of the thermal properties of vital tooth structure, it is not known if the temperature rise in-vivo would be as high. However, to put these values in perspective, a 1997 study on the effect of thermal injury on healthy dental pulp showed

that thermal increases ranging from  $8.9^\circ\text{C}$  to  $14.7^\circ\text{C}$  above an initial average temperature of  $35.7^\circ\text{C}$  did not exhibit evidence of cellular necrosis during histological analysis.<sup>20</sup>

(For additional information on intrapulpal temperature rise during curing and clinical tips to reduce this phenomenon see, ADA Professional Product Review, Volume 8, Issue 2, "Effective Use of Dental Curing Lights: A Guide for the Dental Practitioner.")

### Battery Life

This test measures the battery life of each rechargeable curing unit for one full charge. In this study, the battery life for one full charge is defined as the number of curing minutes that the curing unit can successfully complete before the charge is depleted, as described below.

**Methods.** Each rechargeable curing unit was fully charged before testing. For each test, the curing unit was centered 2 mm over a thermopile, which was connected to a power meter. We then continuously monitored the power output for the curing unit as it was repeatedly operated for cycles of 10 seconds "on" and 20 seconds "off". This 30-second "on/off" cycling of the curing unit continued until the curing unit would no longer operate when the "on" button was pushed, or the irradiance dropped below  $300 \text{ mW/cm}^2$ , which is the minimum requirement specified in ANSI/ADA Standard No. 48 "Visible Light Curing Units."<sup>21</sup>

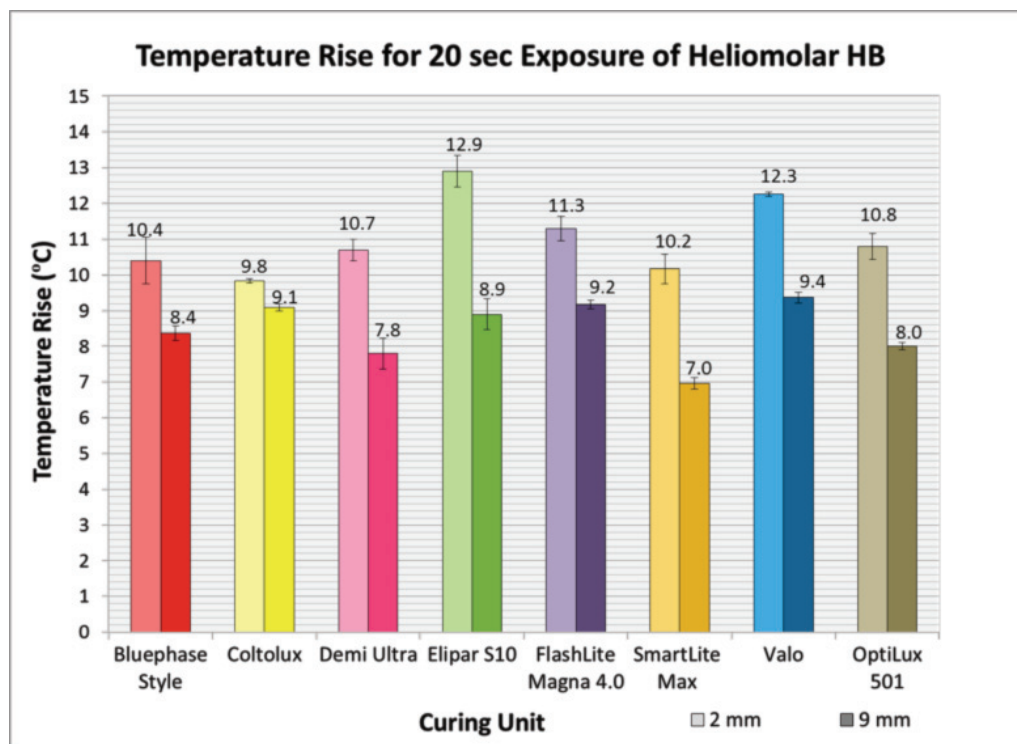


Figure 10. Mean Temperature Rise of Heliomolar HB for Tested Curing Units. For each curing unit, the bars in the graph represent the mean temperature rise, along with the standard deviations, for three tests, with the curing time 20 seconds for each test. The values (°C) for the means are indicated above the bars. The tests were performed in a temperature/humidity chamber with the temperature set at  $36 \pm 1^\circ\text{C}$  and the relative humidity  $50 \pm 5\%$ . The tests were performed with the tip of the curing units at 2 mm and 9 mm from the top of the mold. Note that the tip of the thermocouple is positioned 2 mm below the top of the mold.

The number of 30-second cycles that the curing unit was able to complete was multiplied by the 10-second cure time and then converted and rounded down to the nearest minute. The result is the battery life for one full charge in minutes of cure time.

**Results.** Table 7 lists both the manufacturers' stated battery life for one full charge and the battery life for one full charge as tested in the ADA Laboratories.

During testing, the curing units all showed a relatively constant power output up until the point at which they stopped working because the power source was substantially depleted. Clinically, this means that for one full charge, the power of the respective curing units should not significantly diminish for the curing times shown in Table 7. Instead, when the power source is significantly depleted, the curing units will no longer turn on. However, all of the curing units have an indicator for a low charge, and when indicated, the curing units should be recharged.

From Table 7, the battery life for one full charge of the curing units lasted from 4 minutes (Demi Ultra) to 164 minutes (Coltulux LED). However, the Demi Ultra

curing unit does not actually have a battery as its power source. Instead, it is equipped with an ultracapacitor, which also requires charging. The other curing units use either lithium-ion batteries or lithium-ion technology, including lithium ion polymer and lithium iron phosphate batteries. Although Table 7 shows that the Demi Ultra exhibits a lower amount of cure time per charge than the other curing units, the time required to recharge the curing unit to a full charge is 40 to 70 seconds, compared to hours for the other curing units with batteries.

### Summary & Conclusion

The color-coded beam profile images obtained in this study show that irradiance distribution varied across the light beam for all of the LED curing units (Figure 3). Therefore, when a single irradiance value is reported for an individual curing unit, it is important to consider how it was measured. In this study, in addition to the beam irradiance profiles, we report single irradiance values, which we calculated from the radiant power striking a "clinically relevant" area.

When comparing the beam-irradiance profiles with the single irradiance values measured from the different curing units, the single-irradiance values may be highly misrepresentative of the wide distribution in irradiance values that can be measured across the light beams coming from some of the curing units.

The existence of non-uniform irradiance distributions across the light-emitting tips of the curing units, the presence within the curing units of multiple LED chips with different spectral emission wavelengths, or both, means that the position of the curing unit could have a significant effect on both the radiant power and wavelength of the light received by the resin-based composite material. Both of these factors could result in suboptimal curing.

For the depth-of-cure tests, it is important to note that as the distance increased from 2 mm to 9 mm and the 20-second curing time remained the same, the average depth of cure dropped for all of the curing units (see Figure 7). This occurred because the irradiance values decreased significantly for all of the curing units over this distance (see Figure 3). Furthermore, unless the curing unit manufacturers specifically indicated that the users should increase cure time with distance, the cure times recommended by the manufacturers may not cure the resin restoration adequately as the distance from the curing unit tip to the material is increased.

The battery life for one full charge of the curing units lasted from 4 minutes (Demi Ultra) to 164 minutes (Coltolux LED). However, the Demi Ultra curing unit does not actually have a battery as its power source;

instead, it is equipped with an ultracapacitor and requires just 40 to 70 seconds for a full recharge, compared with hours for the curing units with batteries.

### Bottom Line

An LED curing unit may have a non-uniform irradiance distribution across its light-emitting tip, multiple LED chips with different spectral emission wavelengths or both. This means that the position of the curing unit could have a significant effect on both the radiant power and the wavelength of the light received by the resin-based composite material—both of which could result in suboptimal curing. In addition, as the curing unit tip distance above the resin-based composite material is increased from 2 mm to 9 mm and the 20-second curing time recommended by the manufacturer remained the same, the resulting average depth-of-cure and degree-of-conversion values decreased for all of the curing units tested in this study, often below acceptable curing levels. This could result in under-cured composite in a clinical situation. Battery life and recharge times for all units provided sufficient curing time to cure multiple restorations and not interrupt practice workflow.

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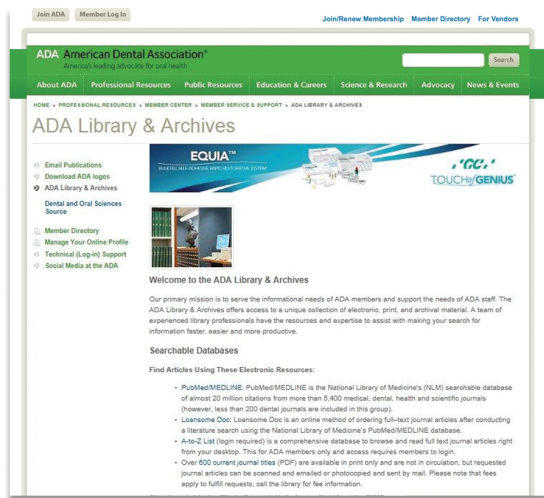
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**ADA** American Dental Association®  
America's leading advocate for oral health

# Product Forum highlights how to improve curing light effectiveness

More than 125 clinicians participated in the ADA Professional Product Review's Product Forum during the ADA's annual meeting in San Antonio last month. This year's forum, "How to Improve Your Curing Light Technique," featured hands-on activities including special patient simulators, a depth-of-cure test and a radiometer station. Participants also received one free CE.

"This was one of the most informative presentations I've attended," said Dr. Dimitri Arfanakis, a general dentist from Douglasville, Georgia. "Learning about the degradation of lights was a big thing."

Participants moved between three hands-on stations. At the first station they used the MARC® Patient Simulator (BlueLight Analytics, Halifax, Nova Scotia, Canada, [www.curingresin.com](http://www.curingresin.com)), which provided clinicians with performance-based results of their curing-light technique in both posterior and anterior positions. The results were displayed in real-time allowing the clinicians to adjust their technique and

benefit from the instant analytical feedback.

"Our colleague, Dr. Howard Strassler at the University of Maryland School of Dentistry is often quoted as saying that training in the all-important process of light-curing is too often limited to the use of just five words:

'...and then you light cure,'" said Colin Deacon, president and CEO of BlueLight Analytics in Halifax, Nova Scotia. "The MARC® patient simulator demonstrates that there can easily be a 10-fold variation in energy density delivered by different clinicians, even when using the same curing light, for the same exposure duration, on the same tooth."

"Our chief science officer Chris Felix and I heard

the same thing over and over through the course of the three-day forum. The dentists' responses were consistent and predictable," Deacon said. Participants' comments included:

*I was surprised by how much the output of a curing light could degrade without my noticing.*

*I did not realize that most curing lights experience a significant drop in irradiance over very small clinical distances.*

*I was not aware that curing lights can deliver a lot of heat, very quickly.*

*I was shocked to see, first hand, how inaccurate radiometers can be.*

*"I always come to the Product Review's Forum," said Dr. Jules Comeau, a general dentist in Long Lake, NY. "I was surprised at all the variables involved with curing—the position of the light, the distance and the shade of the product. It's one thing to read about it, it's another thing to see it [with the patient simulator]."*

.....  
"I had no idea other than point-and-shoot [the curing light]. I'm going to stop talking to my assistant while I'm light-curing."

.....  
"I was amazed at how important stability is when you light cure."

.....  
"I was using a new bulk-fill material and discovered it needed to cure for a longer time."

— Comments from participants at the 2014 ADA Professional Product Review's Product Forum



Chris Felix of BlueLight Analytics (l) and Dr. Gregory Zeller (r) discuss results from the patient simulator demonstration.



ADA research associate Rashad Vinh (standing) works with clinicians on the depth-of-cure demonstration.

A hands-on composite placement and light-curing demonstration allowed participants to use a special stainless steel mold created by ADA researchers. After removing uncured resin, participants measured the height of the remaining polymerized cylinder and divided that value by two to determine the actual depth of cure. (See Figure 1.) ADA research assistant Rashad Vinh assisted dentists with the depth-of-cure test. “Many participants didn’t realize that just because the light is illuminating the mouth,

the required energy is not necessarily reaching the bottom of the restoration, and that was reinforced when we performed the test at different distances and angles.” Vinh said. “They were surprised at the impact that distance, as well as placement of the curing unit made on the restoration.”

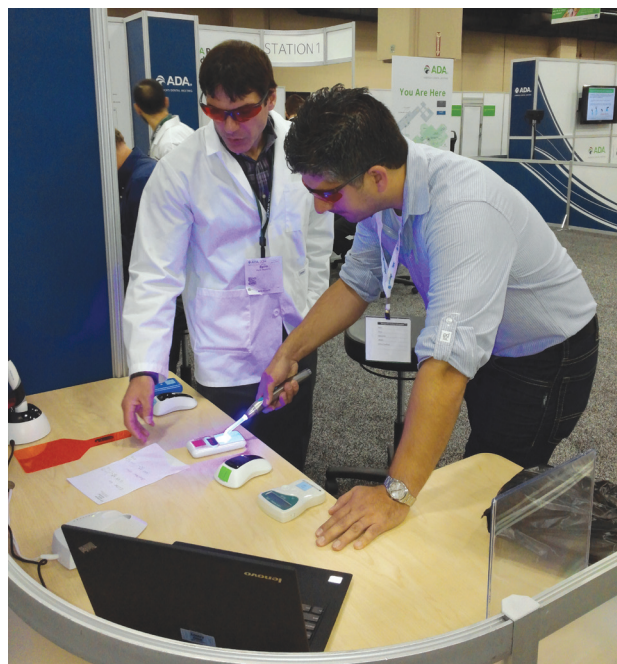
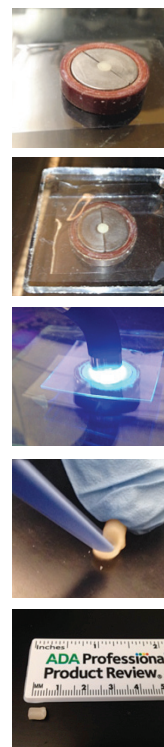
A general dentist for 29 years, Dr. Kristin Fairbanks of Sault Ste Marie, Michigan, said, “For me, this was one of the most clinically significant moments at the ADA’s 2014 meeting. I was able to use [the same model as] my current curing light as they walked me through the science.”

An exhibit of radiometers highlighted the importance of maintaining a dated record of the relative performance of a curing light from the time of purchase and first use so that users can identify when light output begins to degrade. (Editor’s note: A future issue of the ADA Professional Product Review will feature an ADA Laboratory evaluation of radiometers.)

“I just thought an LED light was an LED light, but clearly that’s not the case,” said Dr. Rob Appel, of Beaumont, TX, a 2014 dental school graduate. “I was surprised at how well some of the lights performed but some are very poor. The manufacturers’ claims did not match the reality [of the light’s performance].”

Figure 1. ISO Standard 4049: Depth-of-Cure Instructions

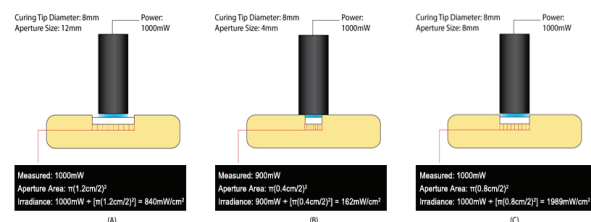
1. Take two pieces of the clear polyester film and place one below the steel mold.
2. Choose a restorative material and slightly overfill the mold with the material, being careful to avoid air bubbles.
3. Cover the mold with the other piece of plastic and press down with the glass to dispel the excess material.
4. Remove the piece of glass and gently place the curing light above the mold opening so that it covers the plastic film and freshly placed material.
5. Cure the material according to manufacturer’s instructions.
6. Immediately remove sample from the mold and scrape the uncured material from the bottom using a plastic spatula.
7. Once all of the uncured material is removed, measure the height of the remaining polymerized cylinder using the ruler provided and divide that value by two to determine the actual depth of cure.



Dr. Spiro Megremis, (l) assistant director, ADA Research and Laboratories and Dr. Dimitri Arfanakis, a general dentist from Douglasville, Georgia (r) discuss the need to monitor curing lights using a dental radiometer. “Keeping a daily log of the output of your curing unit is vital to being able to detect changes in output that may signal a problem with your curing light,” said Dr. Megremis. “Although dental radiometers are useful as a means to measure change in the irradiance from a curing light, their accuracy can be questionable, which is the subject of an upcoming PPR article.”

Figure 2. How Aperture Size Can Affect Radiometer Readings

Typically, dental radiometers measure the radiant power output coming from the tip of the curing light and divide the reading by the area of the radiometer's set aperture to provide an irradiance reading in milliwatts per centimeter squared ( $\text{mW}/\text{cm}^2$ ).



Unless the radiometer's aperture is the same size as the curing light tip, the irradiance values may not accurately represent the curing light's capability.

Figure A: The radiometer is collecting all of the radiant power from the curing light tip. However, the radiometer's reported irradiance value is divided by the area of the radiometer's aperture, which is larger than the area of the curing light tip. This results in an irradiance reading that is artificially low.

Figure B: The radiometer is not collecting all of the radiant power of the curing light tip. The errant radiant power value is divided by an aperture area that is much smaller than the area of the curing light tip, resulting in an artificially high irradiance value.

Figure C: The area of the radiometer's aperture and the curing light tip are the same, which theoretically provides a more accurate irradiance reading. (Other factors can affect a radiometer's accuracy as well.)

Figure 3 A-B. Why Do Depth-of-Cure Values Decrease with Increasing Distance? A Simple Analogy

Figure A shows water from a nozzle sprayed into a bucket. When the nozzle is close to the bucket, all of the water is collected by the bucket. As the nozzle moves away, the water spray is larger than the area of the bucket and not all of the water is collected. The amount of water flowing from the nozzle remains the same, but the bucket collects less water. Thus, it takes more time for the water to collect, because much of it is lands outside the bucket.

A dental curing light behaves similarly as you move it away from the surface of a restoration. In Figure B, the curing light is centered directly above the restoration, and the power radiated from the curing light strikes the area of the composite. However, as the curing light moves further away, the power radiated from the curing light strikes an area much larger than the restoration. The power radiated from the curing light does not change, but there is less radiant power striking the restoration.

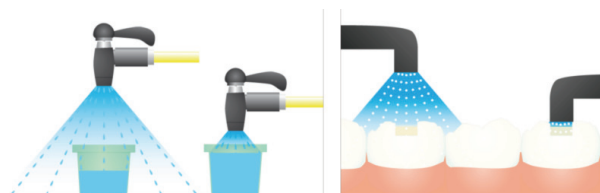


Figure A

Figure B

Power is energy per unit time. So, if less radiant power strikes the restoration, the restoration needs to be cured for a longer time to receive the same amount of energy (i.e., the bucket can still be filled, but it takes longer).

"The PPR forum provided excellent information on the use of curing lights that participants can immediately apply in their daily practice," said Gregory G. Zeller, Associate Dean for Clinical Affairs, and Professor of Oral Health Practice University of Kentucky College of Dentistry. "Scientific information about the characteristics of the lights, such as frequency, power, and light distribution across the tip, was demonstrated in a manner that applies clinically. Demonstrations of the depth-of-cure for composite restorations and of how to monitor curing light output levels on a regular basis were a huge help to me as a clinician. I really appreciate this very pertinent and well-conceived learning opportunity from the ADA — and received free CE credit as an added bonus."

The risks associated with the under-curing of resin composite (e.g., fracture, failure, marginal discoloration) or over-heating of tooth pulp or soft tissue (e.g., post-operative sensitivity), can only be minimized by aligning an accurate measurement of curing light output and curing time, with the energy requirement of the selected brand and shade of resin composite, Deacon said. "It is easy for dentists to take light-curing for granted. The

top surface of resin composite is hard almost instantly, and this can give the dentist a false sense of confidence. Effective light curing is essential if their resin composite is to deliver optimal material properties and clinical performance. It was rewarding to see how quickly the participants connected their use of their curing light to both the clinical risks and success. All of the participants enjoyed the hands-on format that is the cornerstone of the PPR forum."

"For dentists who are new in practice, don't think you learn it all in school," said Dr. Jack Liu, a general dentist in Chicago who has practiced for 30 years. "Keeping up with and understanding dental materials is very important. Take CE courses, do some hands-on classes and talk to your colleagues."

Colin Deacon of BlueLight Analytics (l) and ADA Professional Product Review editor Dr. David Sarrett (r) discussing light-curing techniques.

## Tips for Better Light-Curing

Use protective blue-blocking safety glasses or a shield and always look at the restoration while using a curing light.

Inspect and clean the curing unit before use. Debris or adherent resin on the tip of the curing unit can affect light output and introduce additional infection control risks. Damaged equipment should be replaced.

Just because a curing light emits a blue light, it does not mean that the required energy dose is reaching the resin composite. Irradiance decreases as the distance from the restoration to the tip increases.

The orientation of the light tip relative to the surface of the restoration can affect the amount of light that reaches the top surface and that transmits through to the bottom surface of an increment of resin composite. The tip of the light should be stabilized parallel to the restoration surface and as close as possible without touching.

Every brand and shade of resin composite has a specific minimum energy dose requirement (irradiance x time = energy). For proper curing, you need a sufficient amount of light energy delivered to the polymer at the correct wavelength.

Surface hardness testing using a dental explorer tells you nothing about the depth of cure or the degree of cure even a fraction of a millimeter below the top surface.

Both under-curing and over-heating (of pulp and soft tissues) are risks that need to be managed.

As with all other dental procedures, effective light

curing requires the use of high quality equipment that is properly maintained to ensure consistent performance.

Consistent maintenance includes the removal of resin composite or adhesive from the light tip (as to not reduce light output), replacement of damaged light tips, and monitoring the reduction in light transmission resulting from autoclaving light guides. Additionally, only use an infection control barrier that has been proven to minimally reduce light output.

Radiometers can be helpful for determining whether a light is losing power, but even under ideal conditions they are often not accurate. Maintain a log of radiometer readings for each of your curing lights from the date of purchase so that you can monitor their relative performance over time.

For more information, see Effective Use of Curing Lights: A Guide for the Practitioner in the ADA Professional Product Review, Volume 8, Issue 2.





## Mailbox

In this new feature, we look at some of the most common questions the ADA's Division of Science receives each month from ADA members and their staff.

### Does the ADA have guidelines for the frequency of radiographs?

Yes. "Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure," was updated in 2012 by the ADA Council on Scientific Affairs and the U.S. Department of Health and Human Services Public Health Service and Food and Drug Administration. The guidelines titled, "The Selection of Patients for X-Ray Examination" were first developed in 1987 by a panel of dental experts convened by the FDA's Center for Devices and Radiological Health. The recommendations provide guidance such as diagnosis of new adult and pediatric patients, and recall diagnosis based on caries risk. The development of the guidelines at that time was spurred by concern about the U.S. population's total exposure to radiation from all sources. Thus, the guidelines were developed to promote the appropriate use of x-rays. In 2002, the American Dental Association, recognizing that dental technology and science continually advance, recommended to the FDA that the guidelines be reviewed for possible updating. The FDA welcomed organized dentistry's interest in maintaining the guidelines, and so the American Dental Association, in collaboration with a number of dental specialty

organizations and the FDA, published updated guidelines in 2004. This report updates the 2004 guidelines and includes recommendations for limiting exposure to radiation.

### My patients are asking about triclosan in toothpaste.

#### What can I tell them?

In August 2014, media reports appeared about the safety of triclosan, an ingredient in Colgate Total toothpaste, which received the ADA Seal of Acceptance. According to the U.S. Food and Drug Administration (FDA), "Triclosan is an ingredient added to many consumer products to reduce or prevent bacterial contamination. It may be found in products such as clothing, kitchenware, furniture, and toys. It also may be added to antibacterial soaps and body washes, toothpastes, and some cosmetics—products regulated by the FDA."<sup>1</sup>

Triclosan is the active ingredient in Colgate Total that fights plaque and gingivitis. Colgate Total has a concentration of 0.3 percent of the substance and is the only ADA-Accepted toothpaste that contains triclosan.

The ADA Council on Scientific Affairs monitors and evaluates the safety of Colgate Total Toothpaste on an ongoing basis. "If the council's evaluation determines sufficient scientific evidence exists that an ADA Seal-Accepted product poses a health risk, the council has the

authority to withdraw the Seal from that product," according to the ADA. "At this time there is no clinically relevant scientific evidence indicating that the Seal should be removed from the Colgate Total product."

The Council on Scientific Affairs will continually monitor and evaluate existing and new scientific information on the issue and recommends that consumers continue to follow the U.S. Food and Drug Administration's recommendations on the use of oral health care products that contain triclosan. In addition, the FDA's November 2013 Consumer Update states that the FDA does not have sufficient safety evidence to recommend changing consumer use of products that contain triclosan at this time.

1. Triclosan: What Consumers Should Know. U.S. Food and Drug Administration web site. Accessed August 27, 2014

### Does the ADA have guidance on Ebola?

As of October 24, 2014, dental professionals are advised on the following:

The ADA Division of Science advises dental professionals not to treat dental patients if they have signs and symptoms of Ebola infection because most oral health providers do not have the appropriate equipment, experience and skills to treat safely an Ebola infected patient. The most common signs and symptoms of Ebola infection are:

- Fever (greater than 38.6°C or 101.5°F) and severe headache
- Muscle pain
- Vomiting
- Diarrhea
- Stomach pain or unexplained bleeding or bruising

The ADA Division of Science advises dental professionals to take a medical history, including a travel history from their patients with symptoms or signs in which a viral infection is suspected. The ADA Division of Science suggests the following questions be included into your health questionnaire:

1. Have you travelled to: Liberia, Sierra Leone or Guinea in the last 21 days?

☐ No ☐ Yes

If yes, please let us know when you arrived into the U.S.?

Month \_\_\_\_\_ Day \_\_\_\_\_

2. Are you feeling feverish?

☐ No ☐ Yes

If the patient answers yes to both questions, the individual may be at risk of Ebola. Dental professionals and staff in contact with the patient should:

- Immediately protect themselves by using standard precautions with physical barriers (gowns, masks, face protection and gloves).
- Immediately call 911 on behalf of the patient
- Notify the appropriate state or local health department authorities
- Ask the health department to provide you and your staff with the most up-to-date guidance on removing and disposing of



potentially contaminated materials and equipment, including the physical barriers.

According to the ADA Division of Science, any person within 21 days of returning from the West African countries Liberia, Sierra Leone or Guinea may be at risk of having contacted persons infected with Ebola and may not exhibit symptoms. The ADA recommends delaying routine dental care of these patients until 21 days have elapsed from their trip. Essential treatment and palliative care that is necessary for serious oral health conditions, dental infections and pain can be provided after consulting with the patient's physician and local health department to determine that it is safe to provide such care with standard precautions and physical barriers.

Recent recommendations from CDC request public health authorities to begin active post-arrival monitoring of people whose travel originated in Liberia, Sierra Leone, or Guinea. Active post-arrival monitoring means that travelers without fever or Ebola symptoms will be followed up daily by state and health department for 21 days from the date of their departure from West Africa.

The Ebola virus is spread through direct contact (through broken skin or mucous membranes) with blood and body fluids (urine, feces, saliva, vomit and semen) of a person who is sick with Ebola, or with objects (like needles) that

have been contaminated with the virus. Ebola is not spread through the air or by water, or, in general, by food. Again, there is no reported risk of transmission of Ebola from asymptomatic infected patients.

Information and resources on Ebola are posted on the CDC's website at [cdc.gov](http://cdc.gov). A checklist for healthcare providers (PDF) specific to Ebola is included on the site.

Please revisit this website frequently for further updates.

#### Additional Resources

- OSAP Ebola Toolkit
- CDC Health Alert Network (HAN) — Evaluating Patients for Possible Ebola Virus Disease: Recommendations for Healthcare Personnel and Health Officials
- CDC Recommended Infection Control Practices for Dentistry
- CDC Health Care Provider Preparedness Checklist for Ebola Virus Disease (PDF)
- The ADA Practical Guide to Effective Infection Control (P692)
- The Organization for Safety, Asepsis and Prevention

#### Where can I find the protocol for handling needlesticks in the office?

OSHA requires the dental employer make immediately available confidential medical evaluation and follow-up to an employee reporting an exposure incident. An exposure incident is any eye, mouth, mucous membrane, non-intact skin, or other parenteral contact with blood or other potentially infectious material (OPIM). (For example, a puncture from a contaminated sharp such as an injection needle or a cut from a scalpel blade or suture needle.)

Saliva in dental procedures is treated as OPIM. The dental employer must refer the exposed employee to a licensed health care professional. This means a person who is licensed under the laws of the state where he/she practices to independently provide the post-exposure

evaluation and follow-up services required by the standard. The health care professional will counsel the individual about what happened and how to prevent further spread of any potential infection. He or she will prescribe appropriate follow-up in accordance with current

U.S. Public Health Service recommendations. The licensed health care professional also will evaluate any reported illness to determine if the symptoms may be related to Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV) infection.

Reporting an incident: Employees should immediately report exposure incidents to the employer to permit timely medical follow-up. According to the U.S. Public Health Service, if HIV postexposure prophylaxis is medically indicated it should be initiated promptly, preferably within 1-2 hours after the exposure incident. Immediate reporting also enables the dental employer to evaluate the circumstances surrounding the exposure incident to try to find ways to prevent such a situation from occurring again.

You can find "A Guide to Employer Obligations" on the ADA's web site for more information. You can also read the article, "Safe Injection Practices: Protecting Dentists, Their Staff and Their Patients" in the ADA Professional Product Review, Vol. 7, Issue 3, Winter 2012.

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