3M Science. Applied to Life.™

Scientific Presentation

Elipar™ DeepCure-S
Paradigm™ DeepCure
LED Curing Lights

July, 2017
Dr. Karsten Schwarz

Overview

- Product Description
- 2 Devices – 1 Performance
- Ease of Light Curing and Complication of Incomplete Curing
- Scientific Data
- Clinical Evaluation
- BlueLight Analytics and MARC® Patient Simulator
- Clinical Procedure Case

Elipar™ DeepCure-S and Paradigm™ DeepCure LED Curing Lights:

The Next Generation of Light Curing

No matter how many improvements we see in bonding and composite technology, one piece of equipment is essential to making it all happen…

…the **dental curing light.**

We have improved our curing light technology to ensure a reliable performance.

The Next Generation of Light Curing

3M presents the latest in LED curing light technology:

Two curing lights with identical technical performance:

Elipar™ DeepCure-S
LED Curing Light
(Stainless Steel)

Paradigm™ DeepCure
LED Curing Light
(Lightweight Plastic)

Product Description

- **Intensity** — 1,470 mW/cm²
- **Utilizable wavelength range** — 430–480 nm
- **Black coated light guide**
  optimized geometry provides access to all tooth surfaces without extreme opening of the mouth
- **Easy and intuitive operation**
  with two-button and single-mode operation — no toggle between settings for optimal performance
- **120 minutes of consecutive curing time**
  720 10-second cures with constant light output regardless of battery charge
- **Comfortable, ergonomic, efficient operation**
  V-shaped handpiece and the 360° rotating light guide provide a comfortable grip.
  10-mm tip diameter provides a complete one shot cure of MOD fillings.
- **Easy to clean**
  due to the vent free and sealed housing

2 Devices – 1 Performance

Elipar™ DeepCure-S LED Curing Light

- **One-piece, high-quality, stainless steel housing**
  virtually unbreakable (weight 250 g)
- **Glass ceramic coating**
  offers protection against fingerprints and staining
- **Unique magnetic light guide**
  for quick and easy removal of the light guide for disinfection
- **Charging base with built-in light meter**
  indicating operating status and light intensity

2 Devices – 1 Performance

Paradigm™ DeepCure LED Curing Light

- **Durable, lightweight construction** (weight 180 g) made of shatterproof, high-performance plastic
- Battery charging with **Charging Plug**

2 Devices – 1 Performance

Elipar™ DeepCure-S and Paradigm™ DeepCure LED Curing Lights

The Elipar™ DeepCure-S and Paradigm™ DeepCure LED Curing Lights are identical in technical performance. All data presented here is applicable for both curing lights.

Throughout the remainder of this presentation the curing lights will be referred to generically in text as 3M™ Curing Lights.

Complications resulting from incomplete light curing:

Inadequate polymerization will result in less than optimal properties and poor clinical performance of composite restorations. Mechanical and thermal properties are degraded when the composite fails to reach a **minimum of 80% of ideal cure hardness**:

- Deterioration of margins
- Decreased bond strength
- Reduced hardness
- Greater cytotoxicity

This might lead to **replacement** of the restoration due to:

- Secondary caries
- Restoration and tooth fracture
- Staining/discoloration
- Wear
- Pulpal irritation/post-op sensitivities or even pulpal death

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Light = Light: Or how to know the right light?

Current estimates suggest there are more than 40 manufacturers and **150 different models** of light curing units available on the market today. New ones are introduced every year.

As one may expect, there is a lot of variation amongst the units:

- Price range: $9 – $4,900
- Irradiance range: 400 – 5,000 mW/cm^2 (as stated by the manufacturer)
- Incremental cure time: 1 – 60 seconds
- Cooling: air vs. water vs. no cooling system
- As many as 6 different curing modes

=> Outcome is varying degrees of performance!

Scientific Data

Light Transmission

Light transmission in SiO_2 brine
Source: 3M internal data

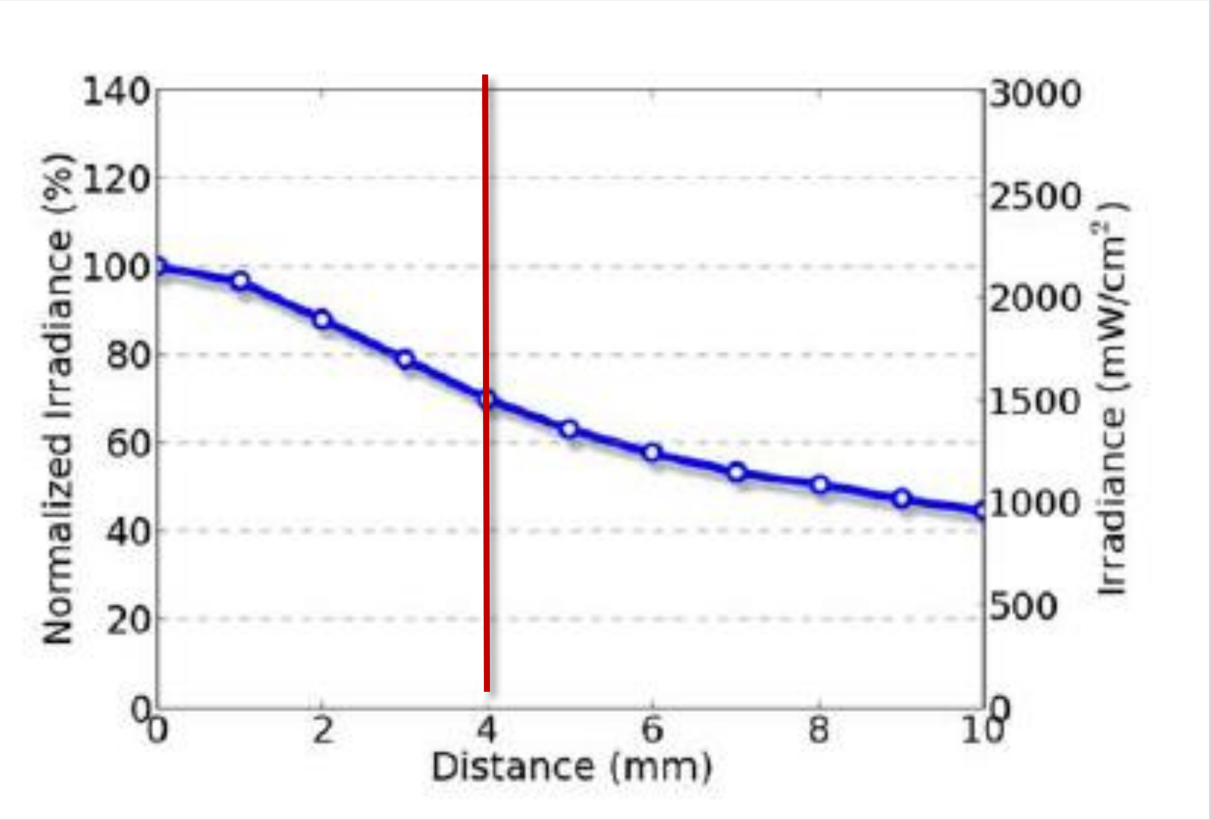
Light penetration shows a **more uniform beam profile and deeper transmission** of light for 3M™ Curing Lights compared to competitive curing lights. The decrease in irradiance over distance **might not deliver enough energy** to cure composite restorations especially in deep cavities which may result in **inadequate light curing of restorations** and **eventual failures.**

Irradiance Over Clinically Relevant Distances

Irradiance measurements taken at **clinically relevant distances** between surface of the resin composite and the light tip provide more **significance to dentists** than tip irradiance measurements.

The 3M™ Curing Light still delivers 70% of its maximum irradiance at 4mm. This allows for a reliable light curing of composite restorations even in deep cavities.

The irradiance produced by some curing lights drops quickly and significantly at clinically relevant distances!



Changes in irradiance over clinically relevant distances of Elipar™ DeepCure-S LED Curing Light.
Source: BlueLight Analytics Inc.

3M™ Curing Lights – Equal or Higher Depth of Cure

Depth of cure of Filtek™ Bulk Fill Posterior Restorative cured with the 3M™ Curing Light and three competitive curing lights at 0, 3 and 7mm clinically relevant distance and light tip placed 3mm off centered. Data show **highest depth of cure** for the 3M curing light.

Movements of the light tip during the light curing procedure negatively affect the curing performance resulting in lower depth of cure. The more uniform beam profile of the 3M curing light proves to be **less sensitive to these movements.**

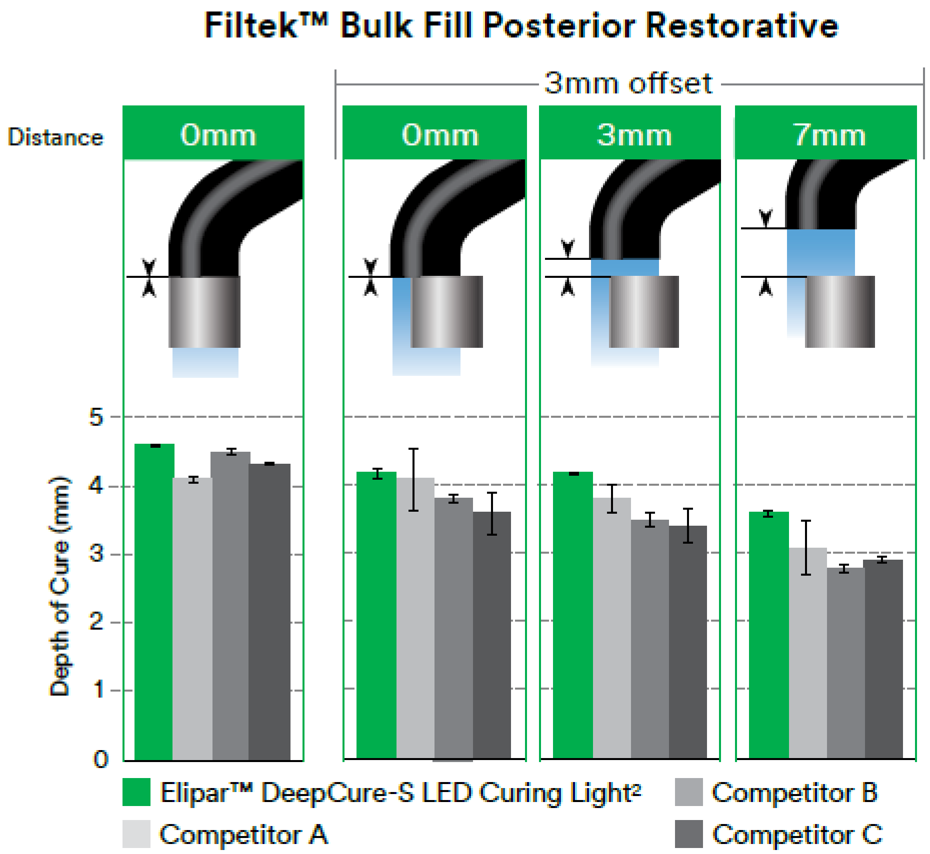


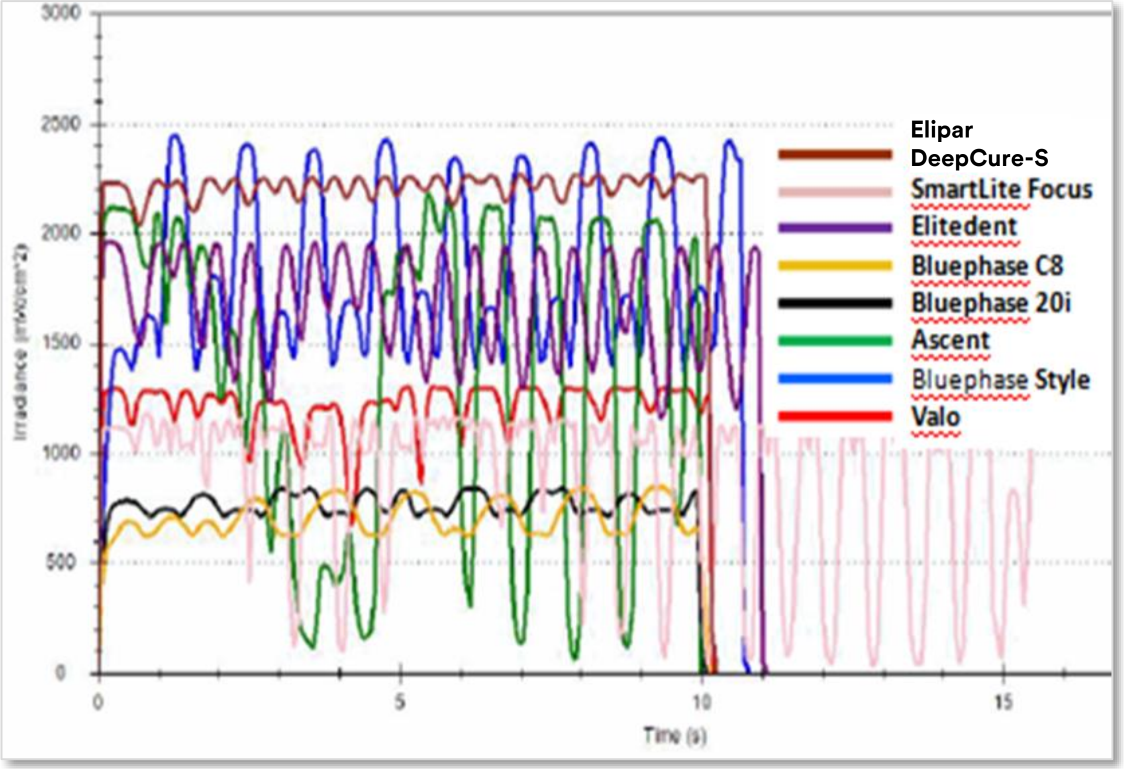
Figure 2: Filtek™ Bulk Fill Posterior Restorative Shade A3, curing time 20 sec. (according to Instructions for Use).
Source: 3M internal data

Impact of Tip Movements On Irradiance Distribution

Moving the curing light tip a few millimeters off the optimal curing position can greatly reduce the curing efficacy. e.g.:

- light is not centered over the restoration
- variation in tip distance to restoration from 0 to 10mm.

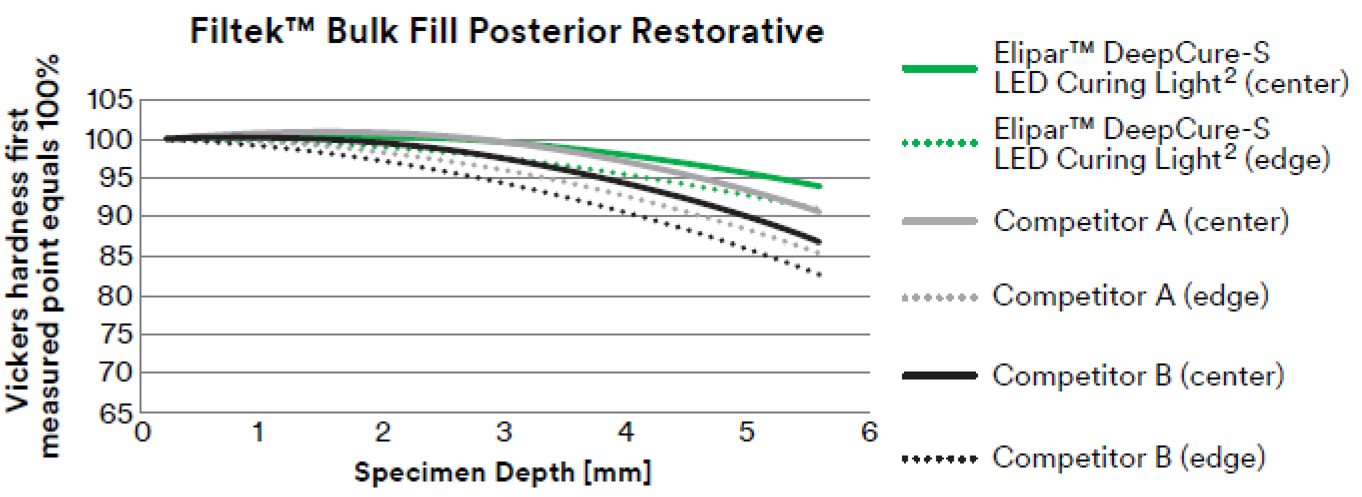
The optimized beam uniformity of 3M™ Curing Lights **maintains intensity over a greater range of distances** — horizontal, vertical and angular movements — allowing the clinician consistent, high quality results at all clinically relevant distances.



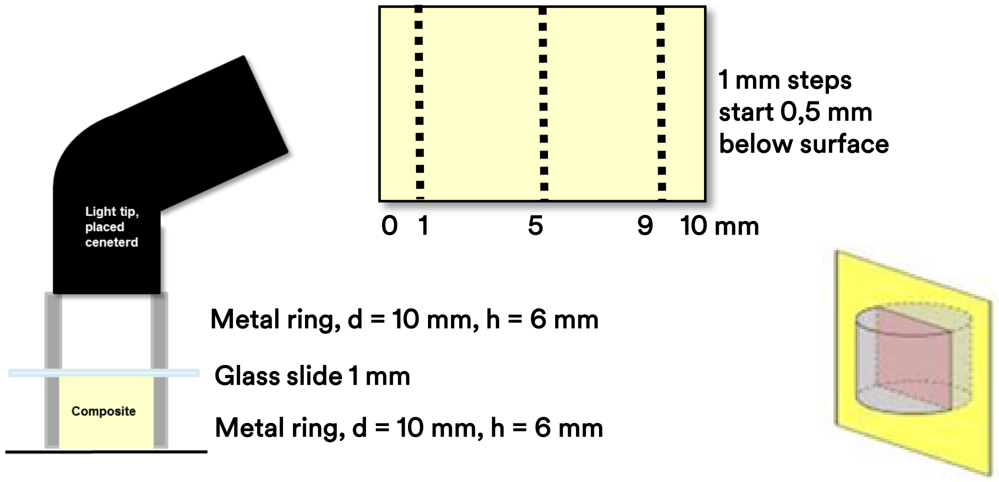
Comparison of the intensity by moving the curing lights ±4mm horizontally measured with the Marc Resin Calibrator. Source: 3M internal data

Vickers Hardness

Comparison of the **hardness profile** of Filtek™ Bulk Fill Posterior Restorative light cured with three different curing lights. To analyze the **polymerization quality** within 6 mm high and 10 mm diameter disc shaped specimens, hardness profiles through the middle as well as at 4 mm left and right from the middle of the specimens were measured with a automatic micro hardness indenter.



Filtek™ Bulk Fill Posterior Composite A3, 20 sec. light curing, 24h water storage at 36 °C
Source: 3M internal data



Correlation Between Beam Profile and Resin Microhardness

Objective:

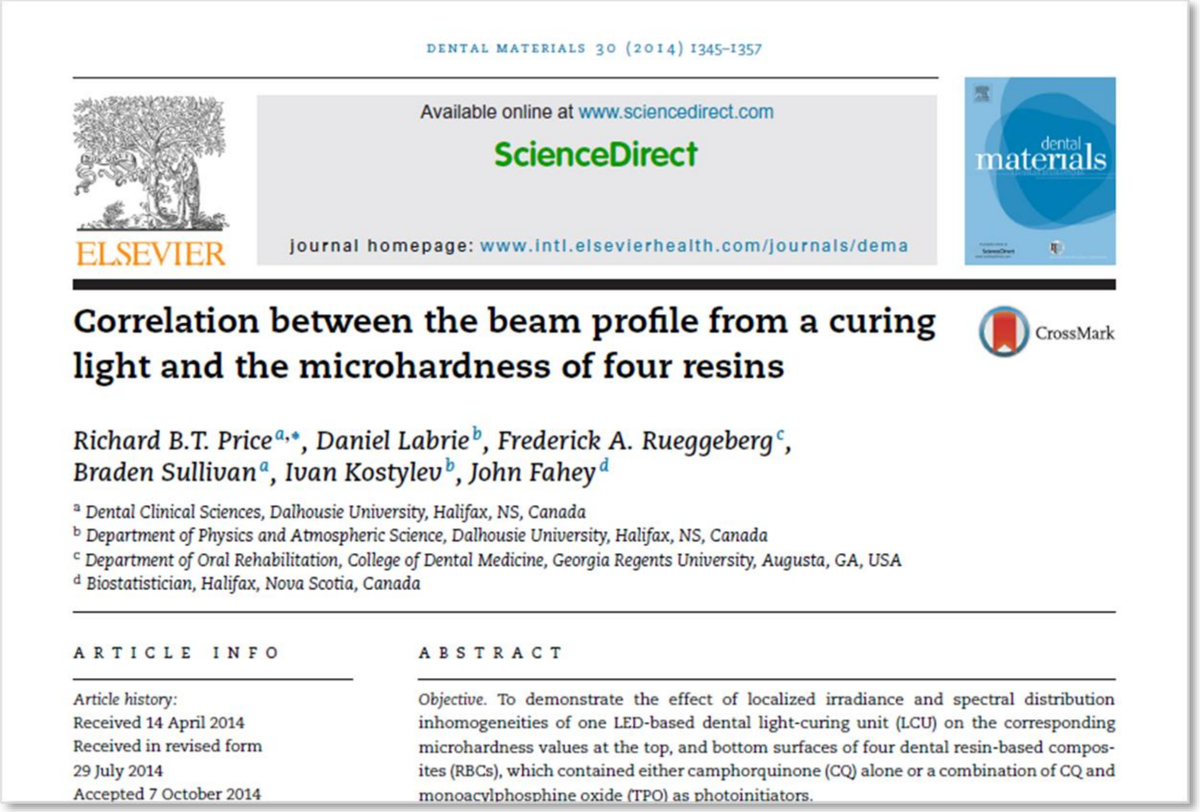
To demonstrate the effect of localized irradiance and spectral distribution inhomogeneities of a curing light on the corresponding microhardness values at the top, and bottom surfaces of four dental resin-based composites.

Results:

Local irradiance and spectral emission values **were not uniformly distributed** across the light tip. There was a **strong significant positive correlation** with the irradiance beam profile values taken through bandpass filters and the microhardness maps.

Conclusion:

Localized beam and spectral distributions across the tip end of the light guide **strongly correlated with corresponding areas of microhardness** in both the top and bottom surfaces among four resin-based composites with different photoinitiator contents.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Correlation between the beam profile from a curing light and the microhardness of four resins

Richard B.T. Price[a,*], Daniel Labrie[b], Frederick A. Rueggeberg[c], Braden Sullivan[a], Ivan Kostylev[b], John Fahey[d]

[a] Dental Clinical Sciences, Dalhousie University, Halifax, NS, Canada
[b] Department of Physics and Atmospheric Science, Dalhousie University, Halifax, NS, Canada
[c] Department of Oral Rehabilitation, College of Dental Medicine, Georgia Regents University, Augusta, GA, USA
[d] Biostatistician, Halifax, Nova Scotia, Canada

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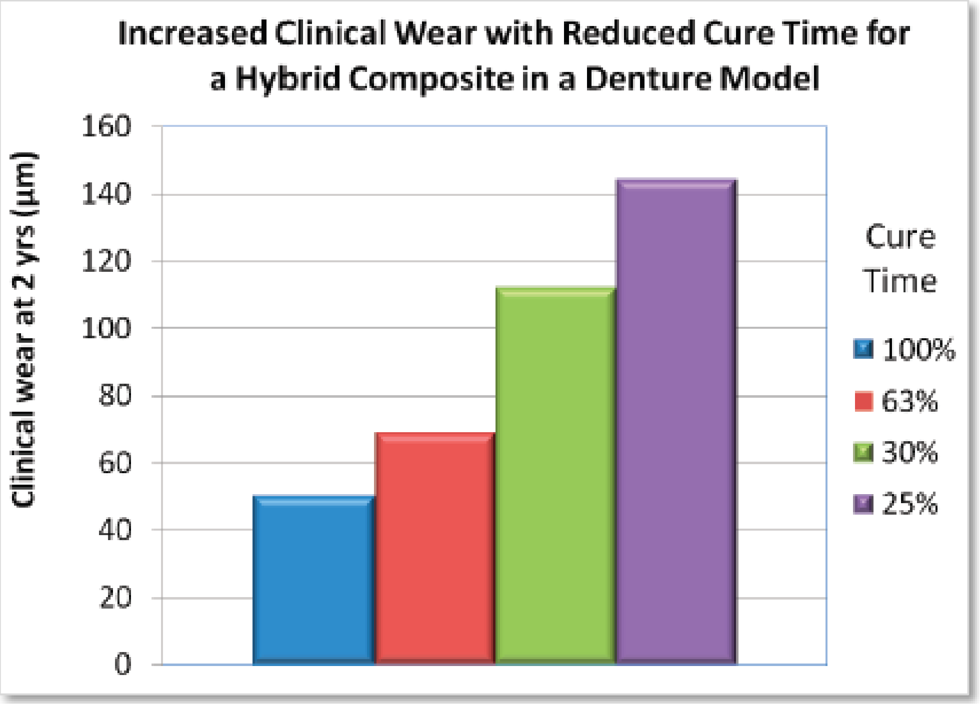
ABSTRACT

Objective. To demonstrate the effect of localized irradiance and spectral distribution inhomogeneities of one LED-based dental light-curing unit (LCU) on the corresponding microhardness values at the top, and bottom surfaces of four dental resin-based composites (RBCs), which contained either camphorquinone (CQ) alone or a combination of CQ and monoacylphosphine oxide (TPO) as photoinitiators.

Relationship Between Light Energy Delivered and Resin-Based Composite Properties

Based on many scientific publications, light-cured composites must receive adequate light energy to **achieve their intended physical, chemical, and optical properties.**

It is well established that reduced levels of resin polymerization caused by delivering an **inadequate amount** of light, or light at the **wrong wavelengths**, will **adversely affect** many resin-based composite properties.



Increased clinical wear with a reduced cure time for a hybrid resin-based composite in a denture model. Source: ADA Professional Product Review 2013;8,2

Pulpal and tissue temperature increase during polymerization – anything to be concerned about?

Pulp response to externally applied heat

Leo Zach, D.D.S., and Gerson Cohen, D.D.S.,** New York, N. Y*

NEW YORK UNIVERSITY COLLEGE OF DENTISTRY

The ascending severity of pulpal lesions induced by heat as an isolated s is described and illustrated in this study, which is part of a continuing vestigation into the biology of pulpal response. Previous work has descr the reactions of pulp tissue to the complex physical variables of cavity pr ration under many modes of operative procedure.[1-5] In this portion of study, an attempt was made to single out the role of heat as the most sig cant variable,[6] without the superimposed effect of cavity preparation, me ments, or fillings on the pulp.

Every stress that is borne by, or transmitted to, viable dentine induce concomitant response within the dental pulp. Not the least of these str is the heat generated during operative procedures, especially when the am of coolant is inadequate to prevent dissipation of frictional heat. Pulpal cha thus far studied in experimental teeth represent the combined effect of seve dentinal tubules and heating the pulp. Thermogenesis associated with sev operative techniques at high and low speeds, with and without coolants, has graphed, and the total pulpal response has been described.[7, 9] Pulp respo to increased temperatures induced by the application of measured heat sou to the tooth surface have also been reported.[8] Thus far, actual intrapu temperatures correlated with the external heat source have not been repo in vivo. This study, by applying a known heat source and measuring its e intrapulpally in a variety of tooth sizes and shapes, defines the histolog the heat parameter of pulpal stressors.

RESEARCH AND EDUCATION

SECTION EDITOR
LOUIS J. BOUCHER

Temperature threshold levels for heat-induced bone tissue injury: A vital-microscopic study in the rabbit

A. R. Eriksson, D.D.S.,* and T. Albrektsson, M.D., Ph.D.**

University of Göteborg, and Institute for Applied Biotechnology, Göteborg, Sweden

Healing following bone surgery may be delayed or even prevented if the bone cells are severely injured by the frictional heat generated during the surgical preparation.[1-4] However, little is known about the critical temperature that causes a reversible or irreversible bone injury. This critical temperature is popularly believed to be around 56° C because alkaline phosphatase is denatured at this temperature level.[5-8] Studies in which bone reactions to temperatures lower than 56° C have been investigated indicate that bone necrosis may result even if the denaturation point of alkaline phosphatase is not exceeded. Rouiller and Majno[9] described hard tissue injury after heating the rabbit metatarsal or radial bone to 55° C for 3 minutes. In a rabbit experimental model, Lundskog[10] found some histochemical evidence of bone death adjacent to an implanted scald that was heated to 50° C for 30 seconds. In both these investigations and others, indirect methods (histology and histochemistry) have been used for evaluating hard tissue viability. Other studies have shown that conventional histologic evaluations tend to underestimate the true extension of tissue death.[11-13] One reason for the lack of knowledge of the critical temperature of bone tissue is the methodologic shortcoming of defining bone necrosis. Furthermore, the important question is not whether the bone will die, but whether it will survive as a differentiated tissue.

hard tissue changes after heating in the range of 4 50° C.

MATERIAL AND METHODS

Animals and anesthesia

Fifteen adult male and female Belgian hare lop-eared rabbits weighing 5 to 7 kg were used i experiments. During chamber installation an vital-microscopic sessions, the animals were an tized with intramuscular injections of Hyp (U.V.A. Laboratories, Paris, France) at a dose ml/kg body weight and intraperitoneal injectio Valium (Hoffman LaRoche Ltd., Quebec, Cana a dose of 0.5 ml/kg body weight. Where requ supplemental anesthesia with 0.5 ml Hypnorm provided at intervals of 30 minutes.

The thermal chamber

The chamber is a hollow, threaded titanium im (Fig. 1). Two glass rods are glued inside the cha and separated by a space 100 μm wide. A narrow canal runs from the top end of the chamber t vicinity of the glass space. After insertion o chamber into the proximal metaphysis, bone from the surroundings will grow through the space. It is later possible to transilluminate ingrown tissue, which remains in continuity wit adjacent tibial bone, so as to obtain a microscopic i

Journal of Oral Rehabilitation 1997 **24**; 791–801

Clinical and histological evaluation of thermal injury thresholds in human teeth: a preliminary study

P. BALDISSARA, S. CATAPANO & R. SCOTTI *University of Ferrara, School of Dentistry, Department of Prosthodontics, Ferrara, Italy*

SUMMARY The effect on healthy dental pulp of thermal increases ranging from 8·9 to 14·7°C was evaluated. These temperature increases correspond approximately to those caused by certain restorative procedures, such as tooth preparation with high-speed instruments and the fabrication of direct provisional crowns. Two criteria of evaluation have been used in conjunction, a clinical (symptomatic) and a histological one, to assert with greater precision potential damage to the pulp. The results suggest a low susceptibility of cells to heat, which does not appear to be a major factor of injury, at least in the short term. The main cause of postoperative inflammation or necrosis of the pulp is probably the injury of the dentine, a tissue in direct functional and physiological connection with the pulp.

Introduction

It is commonly believed that temperature increases associated with certain dental procedures pose a serious threat to the vitality of the pulp.

Pulp temperature increases of 5·5 and 11·1°C in Macaca Rhesus monkeys caused 15% and 60% irreversible pulpitis, respectively (Zach & Cohen, 1965). Schubert (1957) regarded 41·5°C as the threshold beyond which pulp inflammation occurs. In certain restorative procedures, temperatures can easily exceed these values, especially if the procedures are carried out incorrectly.

The preparation of full crowns with air-cooled high-

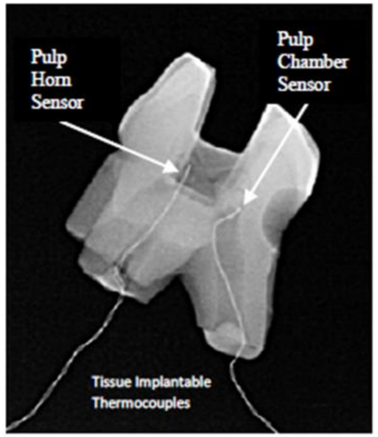
temperature values beyond which the pulp is injured, using thermal stimuli that closely resemble those actually occuring in practice. The determination of threshold values is very important because these are of use in all studies dealing with any of the numerous procedures that cause a temperature increase, in so far as they indicate the values beyond which heat turns from a possible co-factor into a major factor of biological damage. Furthermore, threshold values serve to determine the safety range for instruments or methodologies that cause a temperature increase of dental tissues, and thus avoid negative side-effects.

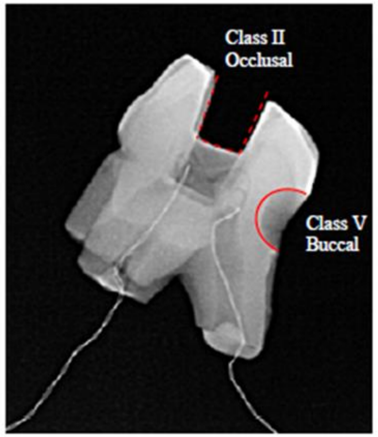
Materials and methods

3M

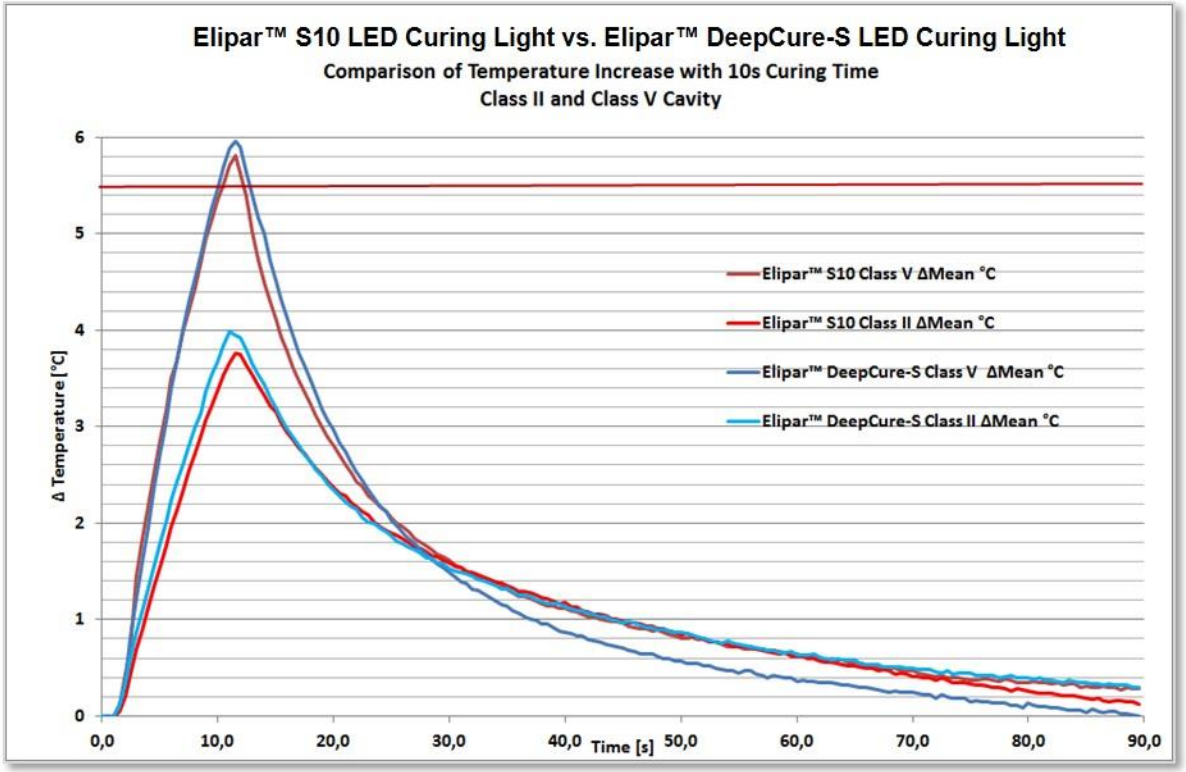
Maximum Pulp Temperature Increase

Human molars were prepared by removing the pulpal material, cutting the roots and inserting thermocouples as shown in the radiographs below. Class II and V preparations were made with 1.5 and 0.5mm of dentin remaining respectively. The tooth was submerged up to the cement-enamel junction in a 35°C water bath.





Statistics showed that this difference is not significant!



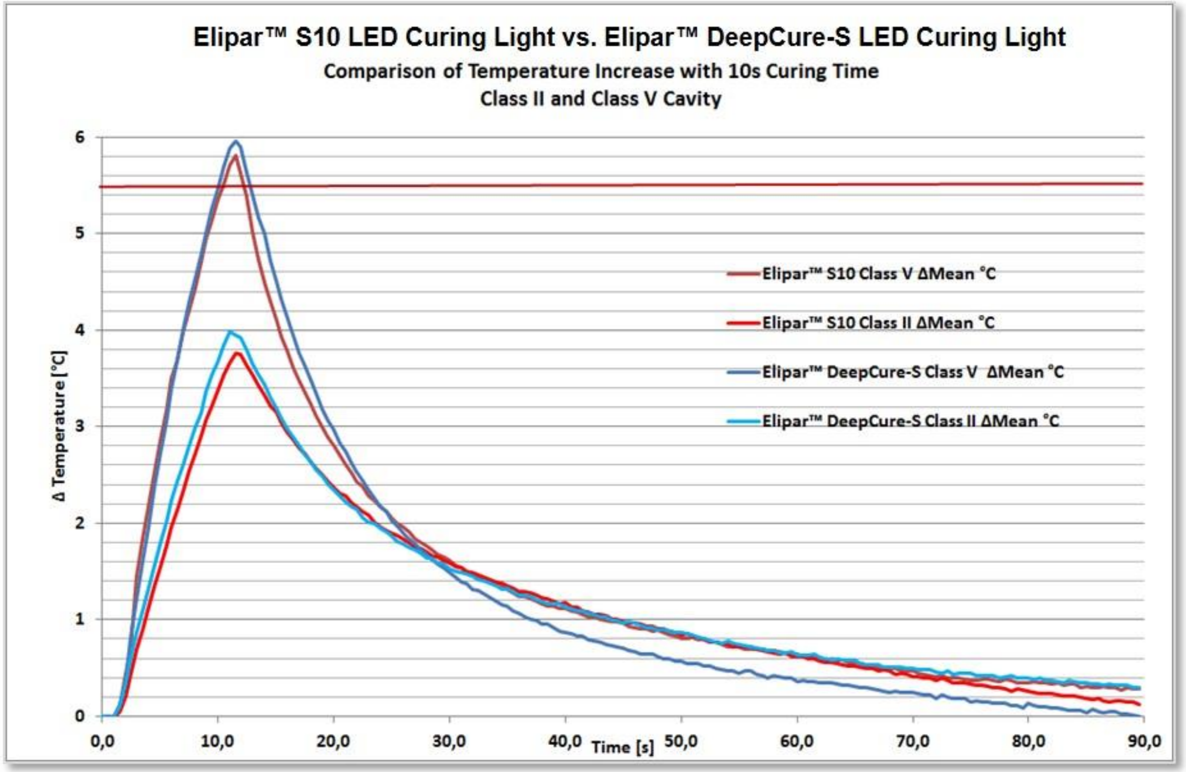
Pulp temperature increase: Changes in temperature within the pulp chamber and the pulp horn of a human tooth placed in a simulated intraoral environment and light cured for 10 sec.
Source: 3M internal data

Maximum Pulp Temperature Increase

Based on current **medical complaint history** on Elipar S10/Elipar/Paradigm LED Curing Lights from 2010 to 2014, 65 medical complaints affecting 69+ patients were reported to 3M.

None of the medical complaints presented a reportable adverse event for this product.

Estimation of number of applications is very difficult since a majority of dental material/dental treatments require light curing. It can be easily assumed that in period of time from 2010-2014 the number of light curing intervals exceeds one billion. **Resulting in a very low number of complaints per million.**



Pulp temperature increase: Changes in temperature within the pulp chamber and the pulp horn of a human tooth placed in a simulated intraoral environment and light cured for 10 seconds.
Source: 3M internal data

Clinical Guidelines to Minimize Thermal Pulp and Tissue Damage

In clinical situations it is very difficult to evaluate the cause of pulpal irritation because the removal of tooth structure is accompanied by physical damage as well as thermal irritation.

To minimize this damage the following 2 steps can help to prevent overheating during polymerization:

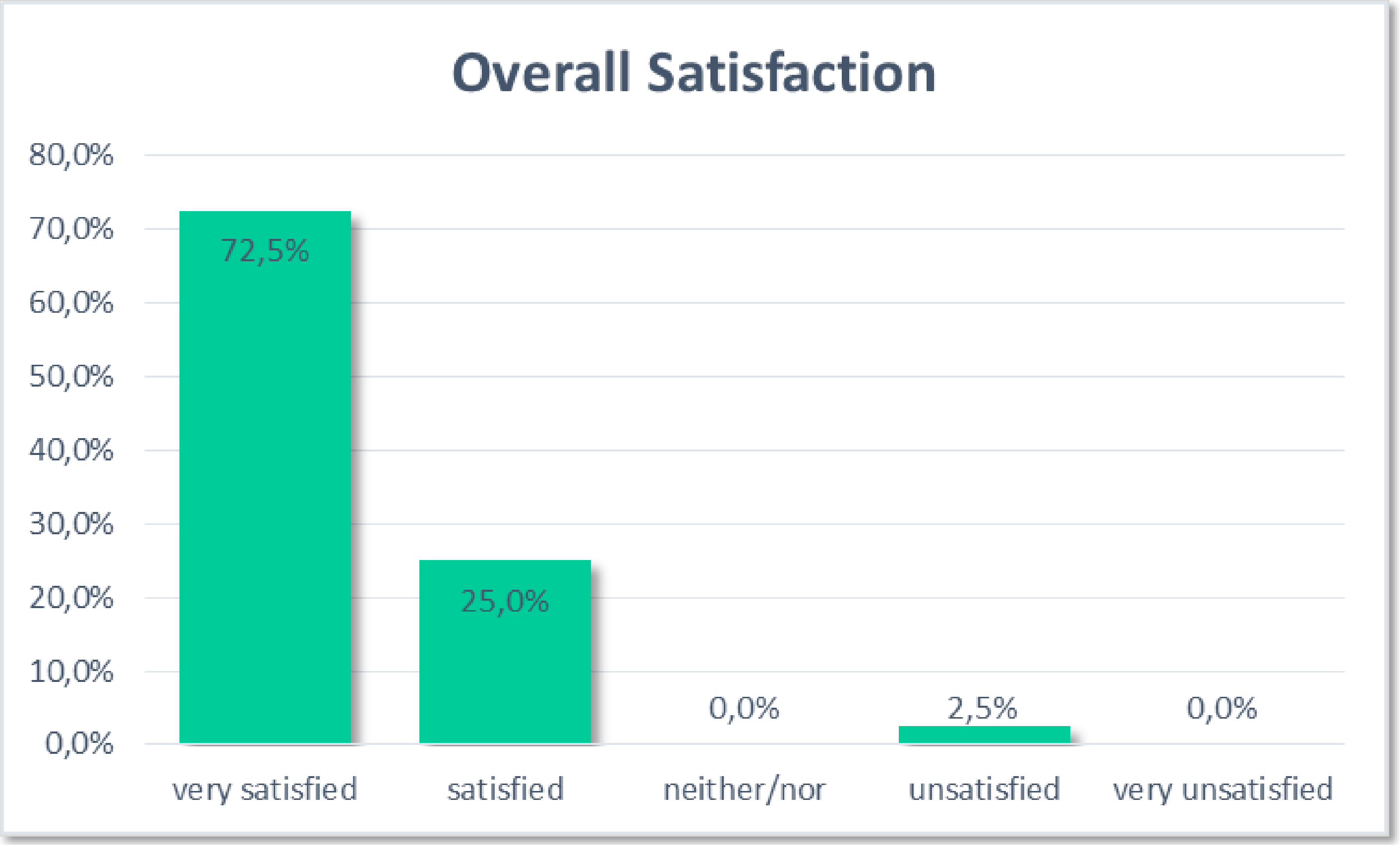
1. **Air-cool** restoration during light curing
2. Break up recommended curing time into **2 curing cycles** with a **short pause in between** the 2 curing cycles
   of 2–3 sec. (e.g. if the recommended curing time for one increment is 20 seconds, light cure twice for 10 seconds with a 2–3 second break between the two curing cycles).

Clinical Evaluation

Field Evaluation conducted with 40 general dentists by 3M in Germany, USA, Turkey and Denmark.

Overall Satisfaction

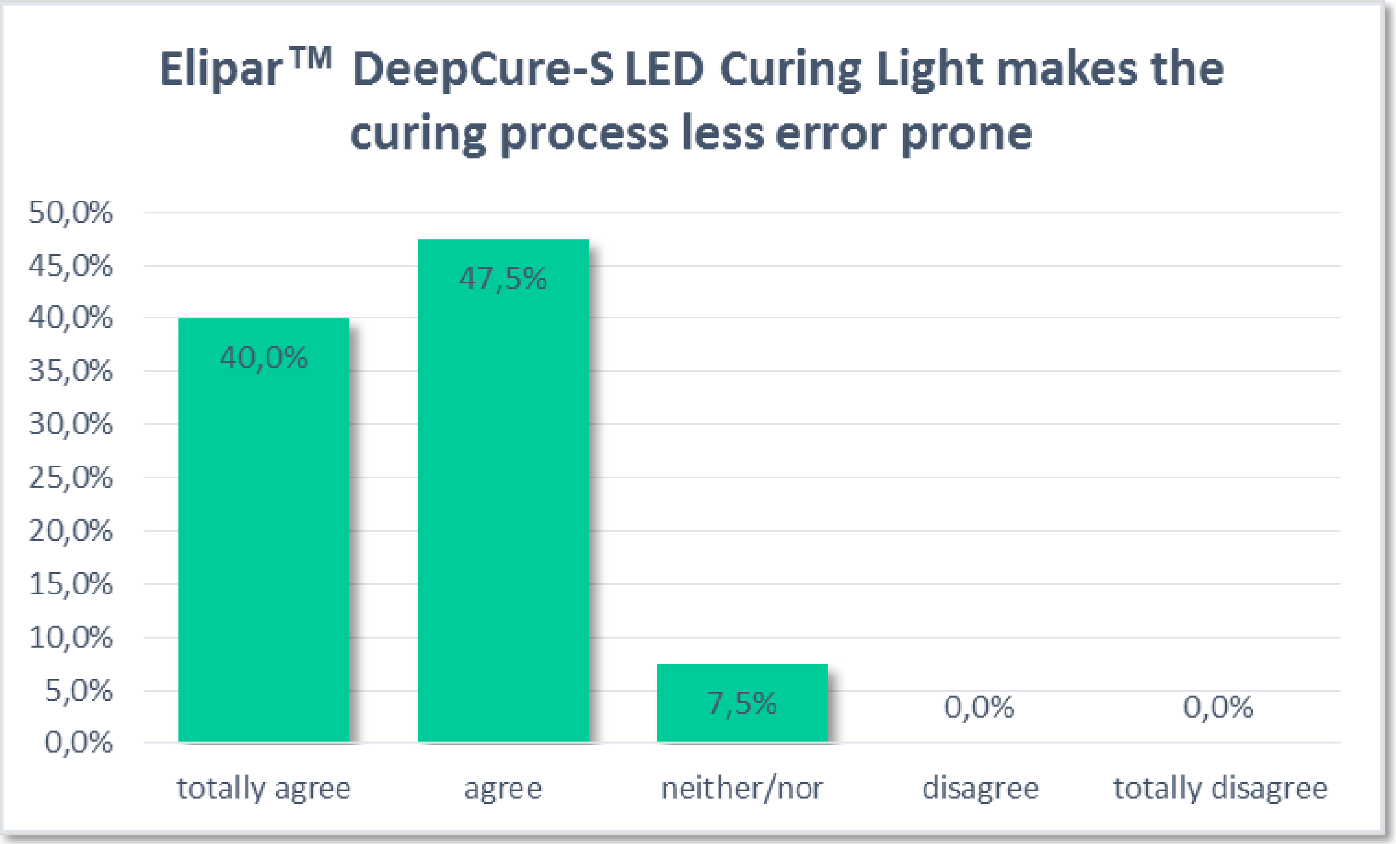
98% of participating dentists were either **satisfied or very satisfied** with the 3M™ Curing Lights.



Source: Field Evaluation conducted by 3M in USA and Europe

Curing Less Error Prone

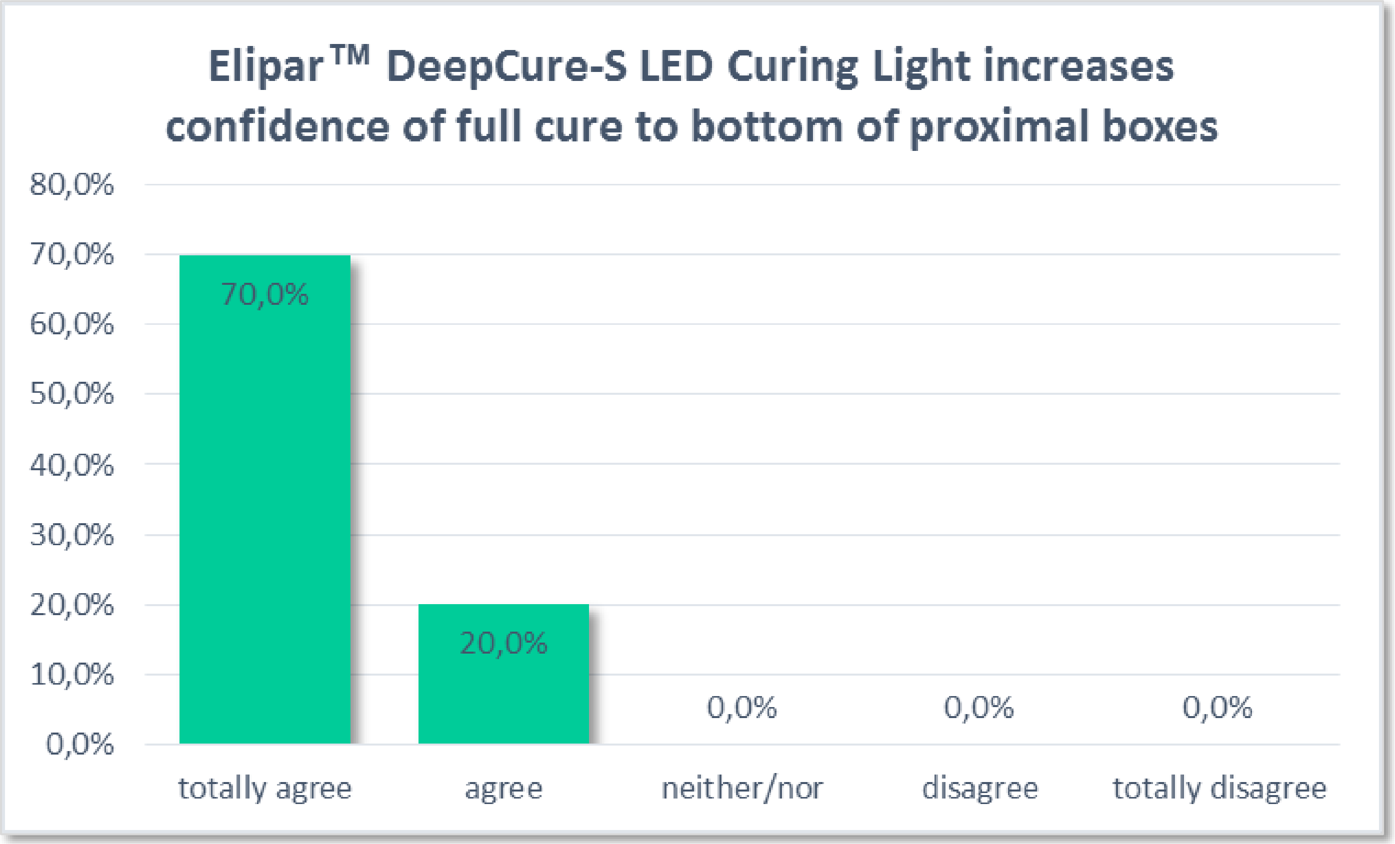
88% of the dentists felt that using 3M™ Curing Lights made the curing process **less error prone** (less sensitive to user variability).



Source: Field Evaluation conducted by 3M in USA and Europe

Confidence of Full Cure

80% of the evaluators felt an **increased confidence of a full cure to the bottom of the proximal box** when curing with the 3M™ Curing Lights.



Source: Field Evaluation conducted by 3M in USA and Europe

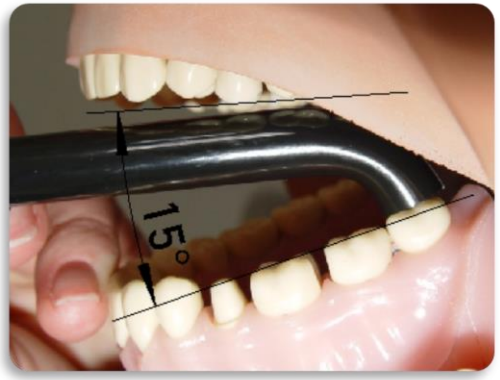
Opening Angle with Different Curing Lights

With the **new light guide** we are now playing in the same class as devices with the LED located in the light guide tip (Valo) and deliver **better patient comfort/ better handling.**

New design of light guide:

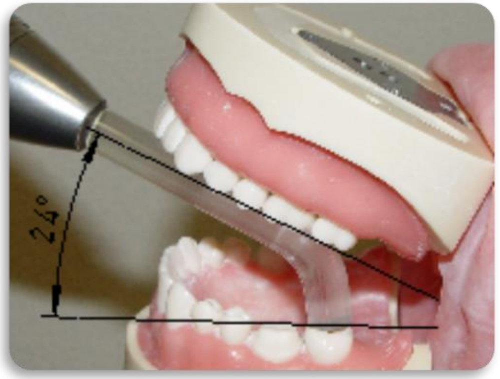
- **black coating** to prevent glare
- **optimized** light guide **geometry**

DeepCure Curing Lights, 3M



Bluephase Style, Ivoclar

Valo, Ultradent



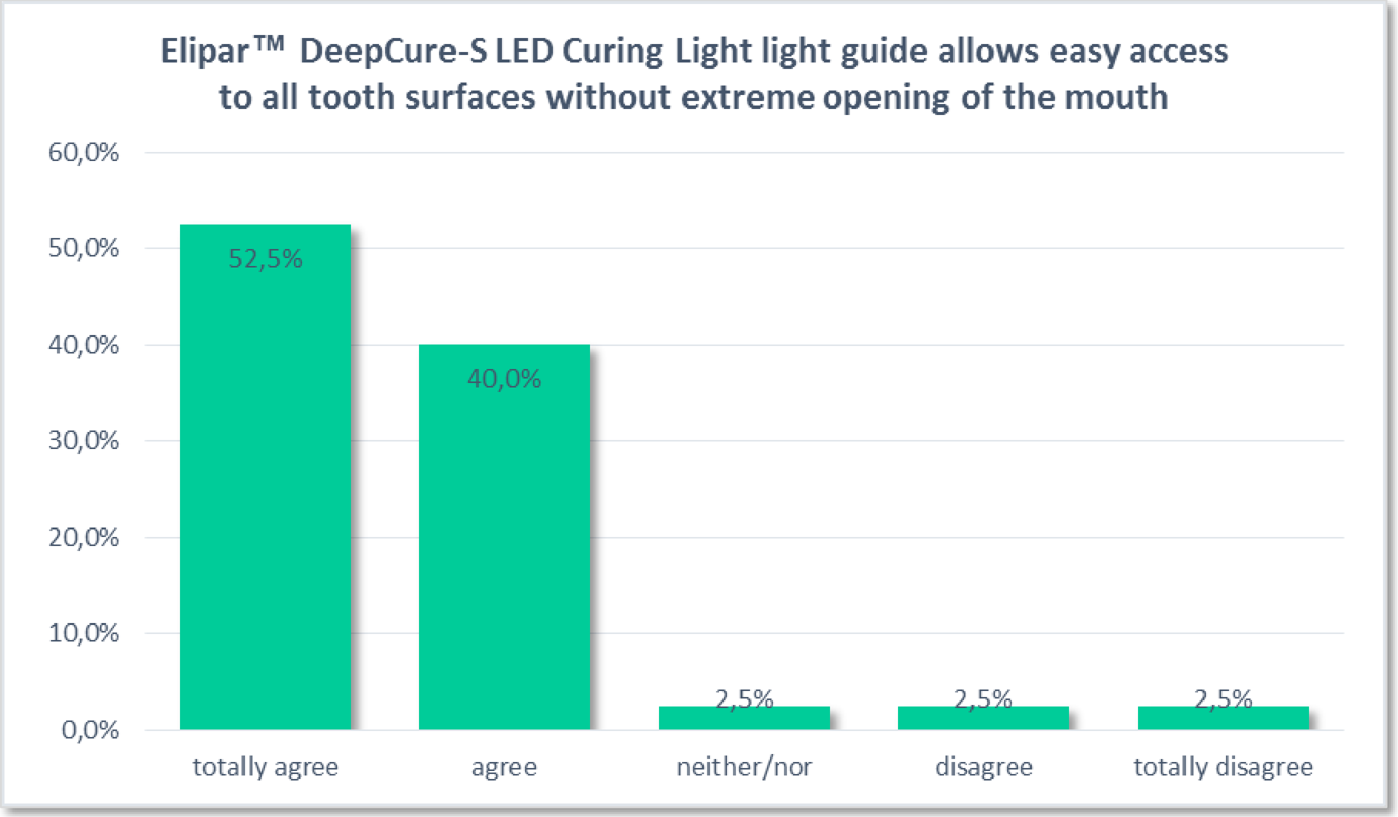
Elipar™ S10 LED Curing Light, 3M

Demi Ultra, Kerr

3M

Easy Access to all Tooth Surfaces

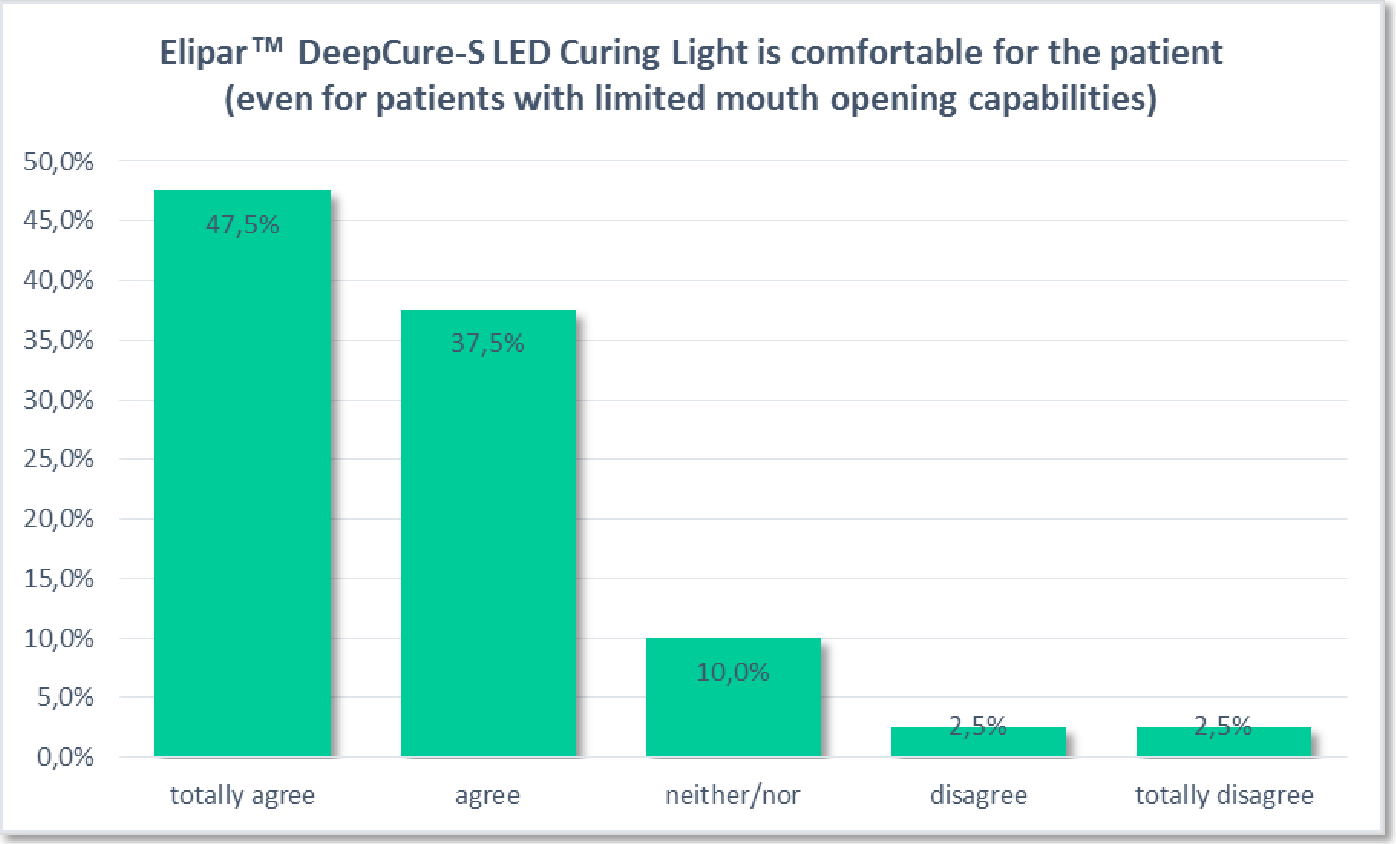
More than 92% of the dentists confirmed that the new light guide design **allows easy access to all tooth surfaces without extreme opening of the mouth.**



Source: Field Evaluation conducted by 3M in USA and Europe

Comfortable for Patient

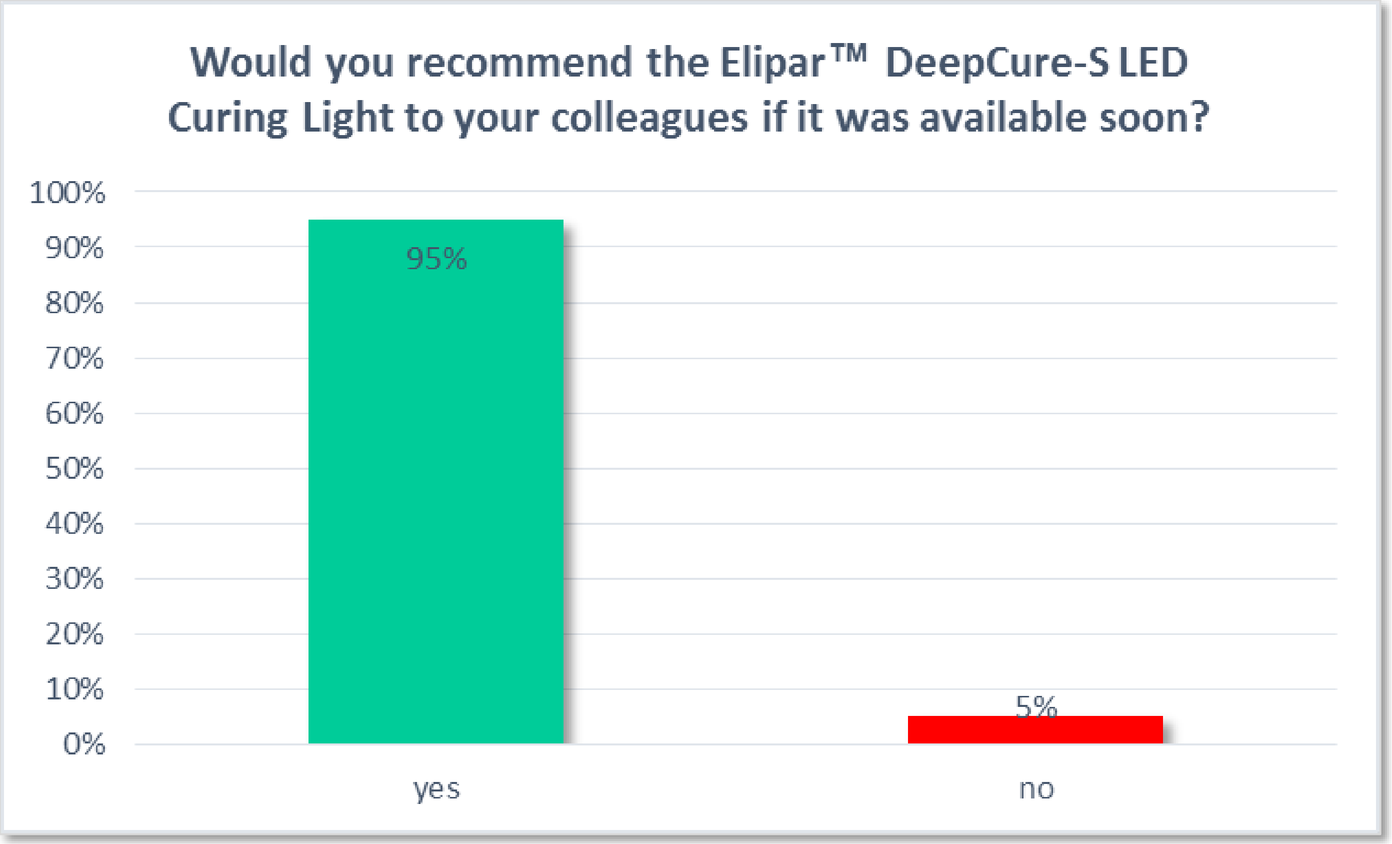
85% of the dentists participating in this clinical evaluation agreed or totally agreed the curing light is **comfortable for the patient** (even for patients with limited mouth opening capabilities).



Source: Field Evaluation conducted by 3M in USA and Europe

Recommendation to Colleagues

95% of the evaluating dentists would **recommened** the new 3M™ Curing Light **to their colleagues** if it was available.



Source: Field Evaluation conducted by 3M in USA and Europe

Light Curing Matters

BlueLight Analytics Inc.

3M

Managing Accurate Resin Curing

MARC® patient simulator the only training system for perfect light curing technique.

Sensors measure the irradiance and wavelength of light energy received by simulated restorations in a typodont head.

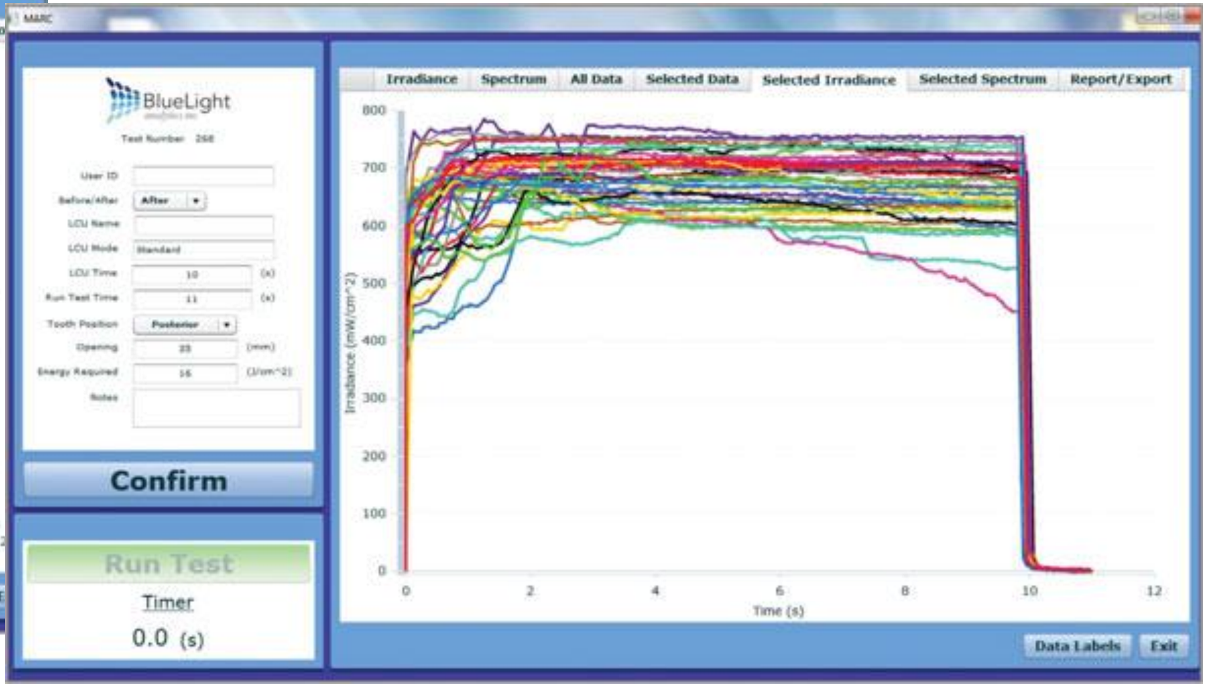
The MARC patient simulator provides both the **physiologically accurate challenges of a restoration procedure** and **real-time analytical feedback of curing light operator performance.**

Students and dentists who have the advantage of simulation-based training are equipped to deliver optimal care.

MARC® patient simulator
Source: BlueLight Analytics Inc.

MARC® Patient Simulator Training

Established performance in real-time before curing technique simulator training.
Source: BlueLight Analytics Inc.



Measured performance improved in real-time after curing light technique simulator training
Source: BlueLight Analytics Inc.

Using the same curing light on the same tooth for 10 seconds, students demonstrate an improvement in light curing technique after simulator training.

The Effectiveness of Using a Patient Simulator

Objective:

To evaluate the effectiveness of using a patient simulator on how to deliver energy optimally to a restoration from a curing light.

Results:

The abilities of dentists and dental students to light cure a simulated restoration were not significantly different. Hands-on teaching using a patient simulator enhanced the ability of dental students to use a curing light. This skill was retained for at least five months.

ADA CE Program ARTICLE 2

The effectiveness of using a patient simulator to teach light-curing skills

Richard B. Price, BDS, DDS, MS, PhD; Howard E. Strassler, DMD; Hannah L. Price; Sachin Seth, BSC, DDS, MEd; Chris J. Lee, DDS, MSc

The teaching and placement of posterior resin-based composite (RBC) restorations have become increasingly popular in the last 10 years.[1] A survey published in 2011 reported that of 46 dental schools, 63 percent no longer taught that amalgam was the preferred posterior restorative material.[2] According to the American Dental Association Survey Center's 2005-06 Survey of Dental Services Rendered,[3] an estimated 146

ABSTRACT

Background. The authors evaluated the effectiveness of using a patient simulator (MARC Patient Simulator [MARC PS], BlueLight analytics, Halifax, Nova Scotia, Canada), to instruct dental students (DS) on how to deliver energy optimally to a restoration from a curing light. Five months later, the authors evaluated the retention of the instruction provided to the DS.

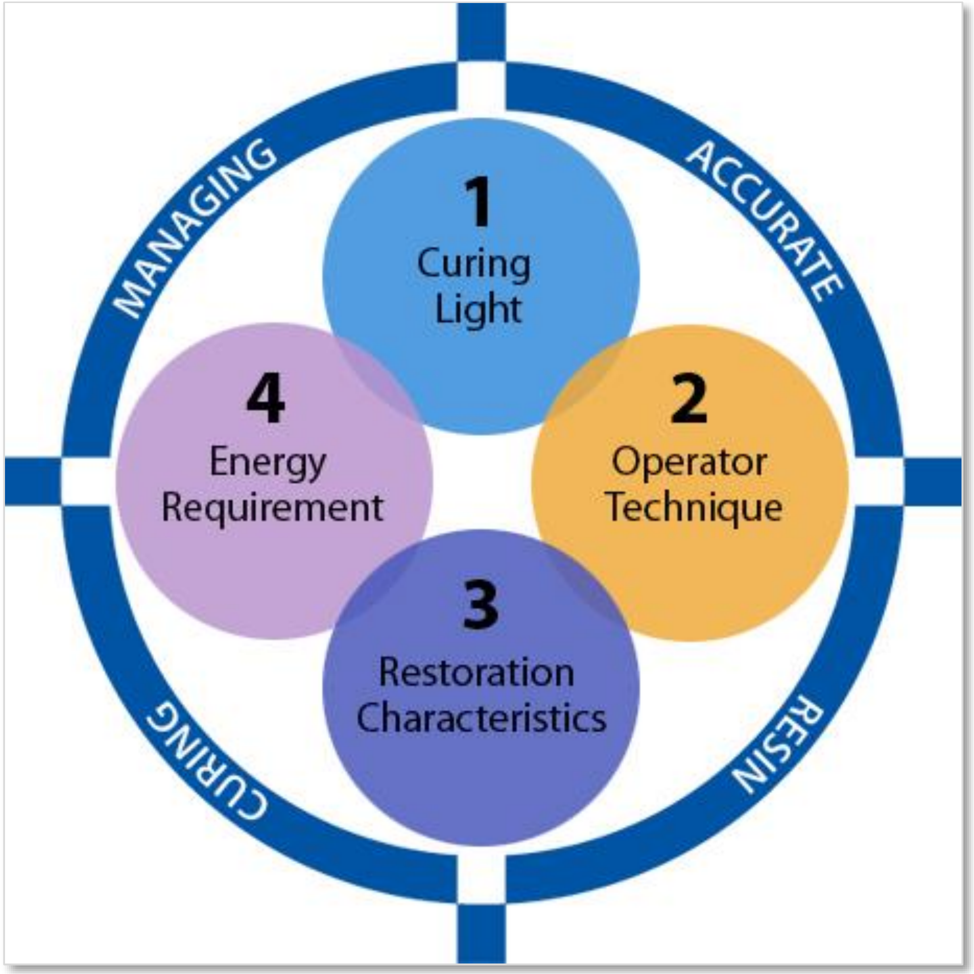
Methods. Toward the end of the DS' first year of dental education, the authors evaluated the light-curing techniques of one-half of the class of first-year DS (Group 1) before and after receiving instruction by means of the patient simulator. Five months later, they retested DS in Group 1 and tested the remaining first-year DS who were then second-year DS and who had received no instruction by means of the patient simulator (Group 2). They gave DS in Group 1 and Group 2 MARC PS instruction and retested them. The authors also the tested fourth-year DS (Group 3) and dentists (Group 4) by using the MARC PS before giving any instruction by means of the MARC PS.

3M

Four CORE™ Variables

The following four sets of variables must be managed by dentists when they light cure intraorally:

1. **Curing lights**, curing modes and light tips can each significantly affect the light's output.
2. **Operator technique** has a direct impact on the amount of energy that reaches the restoration. Proper eye protection, light tip control and proper curing light positioning increases the operator's ability to optimally light cure.
3. The **size, type and location of the restoration** and the patient's mouth opening all affect energy delivery.
4. The **amount, rate, and type of light energy delivered** to light-cured dental material determines the properties of restorations.



Source: BlueLight Analytics Inc.

7 Steps to Successful Light Curing

Providing adequate energy from the curing light is a key factor to the success of resin-based composite restorations. There are important steps to ensure better light curing:

1. Position the patient for optimal view of restoration and easy positioning of light guide.
2. Wear blue-blocking orange glasses or use orange shields for safety and to be able to watch light curing procedure.
3. Position yourself so the curing light can be stabilized in an optimal position over the restoration.
4. Adjust the light guide to provide the optimal access to the restoration. Inspect the tip for any damage or debris.
5. Stabilize the curing light during curing with the beam perpendicular to the surface of the composite.
6. Start curing no closer than 1 mm from the composite and then move as close as possible after the first second of curing.
7. Air-cool the tooth during the curing cycle to avoid overheating the oral tissues. If necessary, break down curing cycle into 2 shorter curing cycles, (e.g. instead of 20 second cure, cure twice for 10 seconds with a 2–3 second break in between).

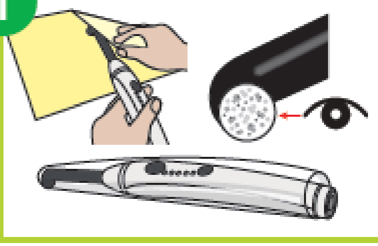
Source: BlueLight Analytics Inc.

BlueLight® analytics inc.

3M

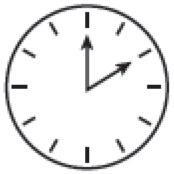
Curing guidelines, according to the Halifax Consensus Statement,* help to assure a safe and proper cure

1



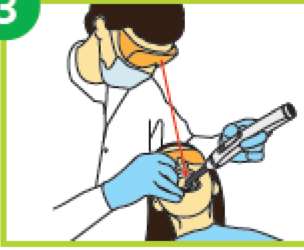
- Clean and inspect tip before and after use

2



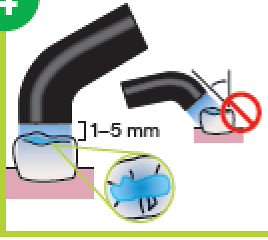
- Set curing time according to manufacturer's instructions

3



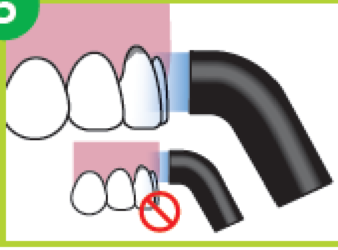
- Wear eye protection
- Stabilize tip
- Monitor position of light while curing

4



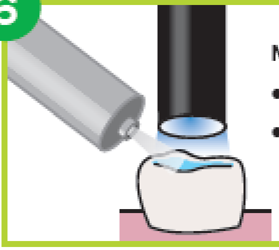
- Cover restoration with tip
- Position tip close and perpendicular to restoration
- Avoid distance > 5 mm and shadows

5



- Verify access to restoration
- Position light to minimize thermal damage to soft tissues

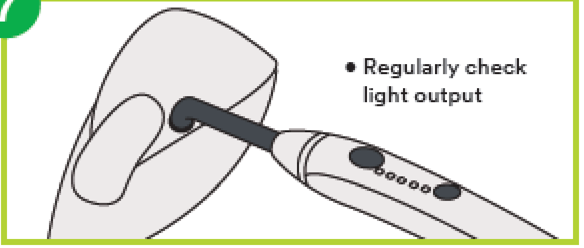
6



Manage heat development:

- Air cool: light on, air on
- Cure in intervals (e.g. 2 × 10 sec. instead of 1 × 20 sec.)

7



- Regularly check light output

Steps 1 through 7 are general guidelines from the Halifax Consensus Statement and may not be applicable to every curing light. For Elipar DeepCure-S and Paradigm DeepCure LED Curing Lights, please refer to Instructions for Use.

*Source: Halifax Consensus Statement from the 2014 Symposium on Light Curing in Dentistry, Dalhousie University, Halifax, Canada

Clinical Procedure Case

3M

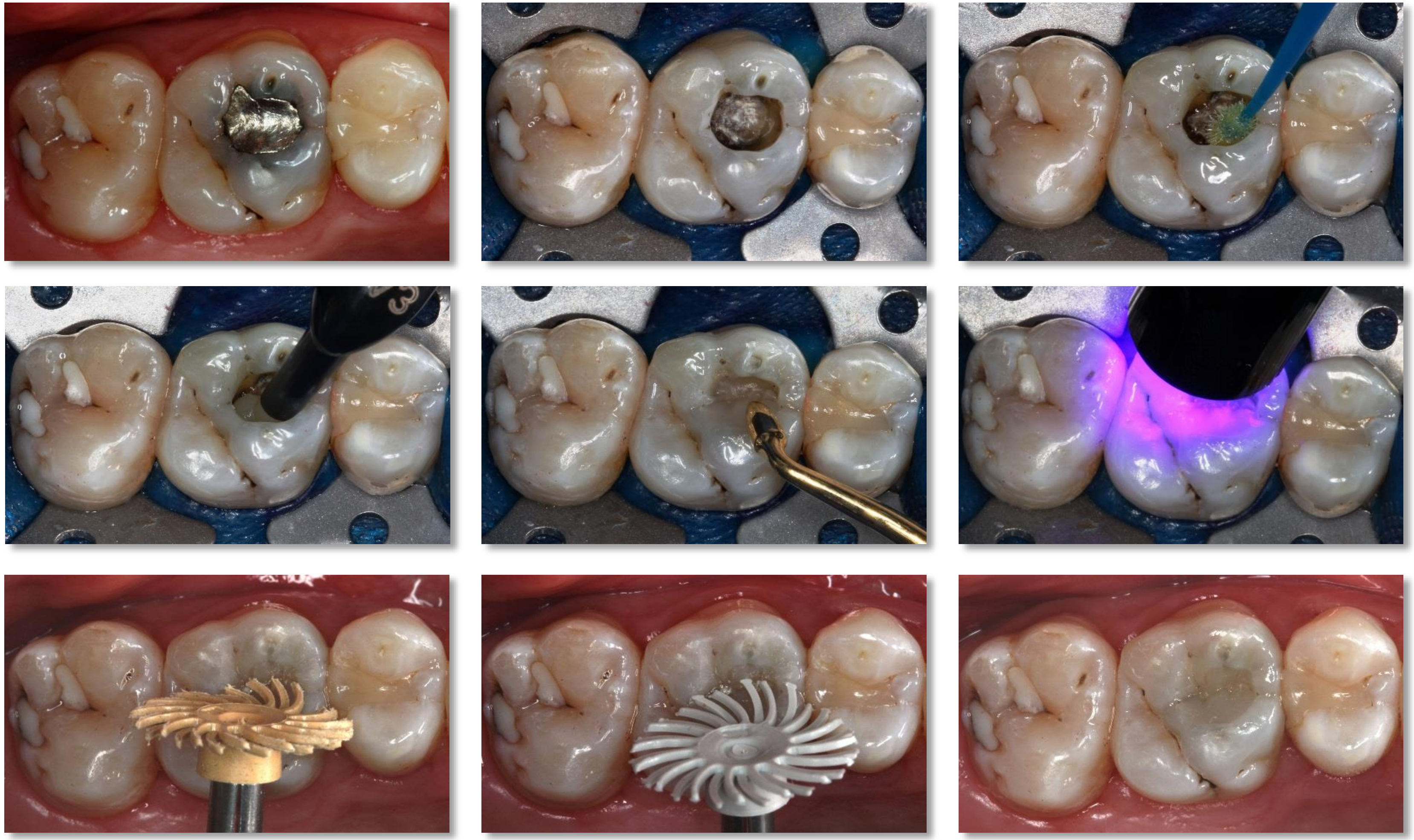
One Simple Procedure, Four Innovative Products

Scotchbond™
Universal Adhesive

Filtek™ Bulk Fill
Posterior Restorative

Elipar™ DeepCure-S
LED Curing Light

Sof-Lex™ Spiral
Finishing/Polishing
System



Case by Dr. Gunnar Reich, Germany

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One Simple Procedure, Four Innovative Products

Scotchbond™ Universal Adhesive

Filtek™ Bulk Fill Posterior Restorative

Elipar™ DeepCure-S or Paradigm™ DeepCure LED Curing Lights

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Thank you.