An Assessment of 1067 Light Curing Units Measured Twice Between 2015 and 2021

ABSTRACT

Introduction: The physical condition of the tip and the irradiance of LCUs used in dental offices in the United States and Canada was assessed twice. Methods: The tip irradiance and physical condition of the tip of 1067 LCUs from 544 dental clinics were assessed twice between 2015 and 2021 using the CheckMARC (BlueLight) radiometer. The irradiance values were compared by paired Student's t-test ($\alpha = 0.05$). Results: There was a wide range of irradiance values (200 to 3,777 mW/cm^2). At the first assessment, only 26% of the LCUs had no visible damage or debris on the LCU tip. When retested up to 36 months later, 70% of the LCUs had their tip damage or debris issues entirely or partially resolved. 2.6% of the LCUs delivered an irradiance below 500 mW/cm^2 on the first and 1.6% on the second assessments. For the 5 brands that had a sufficient sample size, it was concluded that the irradiance increased when the tip damage or presence of tip debris was resolved. Conclusions: Initially, most LCUs (74%) had at least one problem related to damage or debris on the LCU tip. The irradiance increased when the tip damage or debris was resolved.

Keywords

Evaluation
Longitudinal Study
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INTRODUCTION

Light-cured adhesives, resin-based composites (RBCs), luting agents, and sealants must receive sufficient radiant energy (Joules) at the correct wavelengths (nm) from the light-curing unit (LCU) to achieve the material properties claimed by their manufacturer.[1-18] Due to concerns over the mercury in dental amalgam and the demands of patients for tooth-coloured restorations, the number of light-cured RBCs placed is increasing, and the number of dental amalgam restorations placed every year is decreasing.[19] In 2014, 800 million direct resin-based composite (RBC) restorations were placed, and almost all of these restorations required photocuring using an LCU.[20] In 2018, there was a global agreement by the World Dental Federation (FDI) to phase down the use of dental amalgam.[21] With the planned ban on using and exporting dental amalgam in the European Union starting 1 January 2025,[22] the use of RBCs will be further accelerated. Thus, the dental LCU has become an important piece of equipment, and billions of dollars of dental work produced annually depends on the LCU functioning correctly.[1,2,4]

Despite reports from controlled clinical trials that posterior RBC restorations can last 20 to 30 years,[23,24] there is a wide range in the annual failure rate, the survival rates range between 23% and 97.7%, and success rates range between 43.4% and 98.7% for posterior RBC restorations.[25] Several studies have reported that the median longevity of posterior RBCs placed in dental offices is only seven years or even less.[26-29] Of note, one

study published in 2019[30] followed over 31,000 direct class II restorations placed by 22 general dental practitioners (GDPs). The average annual failure rate (AFR) of restorations placed by GDPs over two years was 7.8%, with a range between 3.6% to 11.4%.[30] Restoration replacement due to caries was the most common intervention, followed by endodontic treatment.[30] Given that the authors stated that all the dentists in the study were motivated above average to provide high-quality care, the reason for this wide variation in the longevity of RBC restorations has yet to be elucidated. Still, it appears that how the dentist handles the products may be more critical to longevity than the choice of materials used.[24,25,31] For ethical reasons, it remains to be proven that variations in the adequacy of resin curing might contribute to this clinical difference, but a recent clinical trial has reported that increasing the exposure time for the adhesive from 10 to 40 seconds improved the clinical longevity of non-carious cervical RBC restorations.[32] This clinical outcome is supported by substantial laboratory research showing that delivering an insufficient radiant exposure will negatively affect the photo-polymerization of resins (bonding agents, resin-based restoratives, resin-based luting agents, and sealants), their physical properties, and bond strengths to teeth.[5-18]

It has been estimated that replacing failed restorations accounts for more than half (57%) of the restorations placed by GDPs,[33] and the two most common reasons for replacing RBC restorations are due to fracture of the RBC and secondary dental caries.[24,25,29,34] Failures due to recurrent caries occur most frequently at the gingival margin of the proximal box in Class II restorations.[29,34] Here the bonding resins and the RBC are furthest away from the light-emitting tip of the LCU[35] and the most challenging to reach with sufficient energy,[36-39] especially considering the significant reduction in irradiance from most LCUs as the distance from the light tip increases.[40-42] Thus, the resin at the bottom of the proximal box is likely to be less well photocured than the resin at the occlusal surface. This will negatively affect its physical properties and bond strength to the tooth and will leave more unreacted monomers available to be leached into the oral environment.[5-18,36-38,40,41,43-45] In addition, it has been reported that more biofilm may form in the regions where RBC is undercured[10,45] which could contribute to more secondary caries. Conversely, the soft tissues or the pulp can be damaged if too much light energy (heat) is delivered.[46]

Dental LCUs are classified as Class II medical devices in the United States and China.[47-49] In contrast, they are Class I Medical devices in Canada and the European Union.[50-53] However, any deviation from the LCU manufacturer's instructions for use is considered unsupported 'off-label' use of a medical device. Thus, if the user does not follow the manufacturer's instructions that specifically state that damage or debris on the LCU must be addressed and that the user should regularly test the LCU, then this transfers any liability from the LCU manufacturer to the user. In the US, LCUs also fall under the FDA General Radiological Health Requirements, where a radiation-producing medical device is considered defective if it "fails to conform to its design specifications relating to the emission of electronic product radiation".[54]

The radiant exitance (tip irradiance) and radiant exposure are International System of Units (S.I.) radiometric definitions used to describe the light from LCUs.[1,55] Most dental manufacturers report the tip irradiance, which is the radiant power emitted from a defined light tip area and is usually reported in mW/cm^2. In contrast, the incident irradiance is the radiant power received by a defined area and is usually also reported in mW/cm^2. The radiant exposure is the energy received from the LCU per unit area and is generally reported in J/cm^2. The International Organization for Standardization (ISO) standard 10650 for powered polymerization activators requires that LCUs deliver a radiant exitance (the tip irradiance) that is within ± 20% of the manufacturer's claimed irradiance value.[56] These standards provide measurement methods so that manufacturers can provide specifications for their LCUs and are used to determine the exposure time required to light-cure their resins. Most resin manufacturers[57,58] now recommend delivering a minimum irradiance of at least 500 to 550 mW/cm^2, thus providing a minimum of 10 to 11 J/cm^2 to the RBC in 20 s. Unfortunately, studies worldwide have reported that the light output from many LCUs used in dental offices is lower than 500 mW/cm^2. For example, in one study,[13] it was reported that 33% of the light-emitting diode (LED) LCUs in the United Kingdom delivered less than 500 mW/cm^2, yet most of the operators still used the LCU for the same 20-second exposure time. Another study from Brazil[14] reported that approximately 50% of the LCUs tested delivered less than 300 mW/cm^2, and a 2018 study from Germany[59] reported that about 10% of the LCUs tested delivered less than 400 mW/cm^2. Thus, since many dentists now use the same 10 to 20 s exposure time when light curing any RBC restoration in the mouth, regardless of its shade, opacity, or brand,[13,59,60] an irradiance level of 400 mW/cm^2 that was once considered acceptable[18,61] is now considered unacceptable.

To reduce exposure times and ensure that their resins are adequately photo-cured, dentists rank a high irradiance as the #2 feature (after portability) when choosing which LCU to purchase.[60] However, since most dentists do not own a radiometer, they cannot measure or monitor the irradiance from their LCU.[13,59,60,62-66] Instead, they rely on visual inspection of the light output. Unfortunately, the human eye cannot detect if the light output from the LCU is inadequate. This is concerning because although the top surface of the RBC may appear hard to the dental explorer, the resin at the bottom of the restoration may be undercured if insufficient energy is delivered.

There are a few commercially available dental radiometers, such as the Bluephase Meter II[67-69] (Ivoclar, Amherst, NY, USA), the CheckMARC (BlueLight Analytics, Halifax, Nova Scotia, Canada)[70,71] or the CheckUP (BlueLight Analytics),[12,72] that are sufficiently accurate to measure the light output from LCUs

to within ± 10%. However, the CheckMARC and CheckUP devices also upload the data they record to BlueLight Analytics. Personnel at BlueLight Analytics then provide the operator with further information to ensure that appropriate exposure times are used. (https://www.BlueLightanalytics.com/solutions/checkmarc). Thus, while a dental office could regularly measure and record the light output from the LCU using their radiometer, BlueLight Analytics does this automatically every time the same LCU is tested, and they can notify the dentist if the output from the LCU is falling.

To the authors' knowledge, no study has yet reported the results of retesting the same LCU used in dental offices/clinics at some later date after the user had been given additional instructions on how to maintain their LCU. Consequently, this study examined 1067 unique LCUs in dental offices that had been assessed twice between 2015 and 2021 using CheckMARC. The following hypotheses were tested:

1. All the LCUs tested would be free of tip damage and debris and compliant with the ISO standard,[56] which requires them to deliver an irradiance within ± 20% of the manufacturer's claimed irradiance value.
2. When retested, the LCUs previously identified as having issues with the tip or the irradiance had their issues resolved.

MATERIALS AND METHODS

In this study, an acceptable LCU is defined as one that meets the manufacturer's specifications. Thus, the LCU should be in good working order, free of tip damage and debris, and deliver an irradiance within ± 20% of the manufacturer›s declared value.[56]

The CheckMARC (BlueLight Analytics) was used to measure the LCUs in the participating dental offices located in the United States and Canada. The CheckMARC contains an STS spectrometer (Ocean Insight, Orlando, FL, US) with a range of 350 to 800 nm. The CheckMARC device has a 16 mm aperture and a large sensor so that all the light output from the LCUs was collected. The STS spectrometer was calibrated using a NIST traceable calibration lamp (HL-2000 Tungsten Halogen Light Source, Ocean Insight), and the quality assurance team at BlueLight Analytics reviewed all the LCU measurements.

Representatives from a dental materials manufacturer (3M) in the United States (n=82) and Canada (n=18) were first trained by BlueLight Analytics on how to examine the tips of the LCUs and how to use the CheckMARC radiometer to measure the irradiance. These representatives were instructed to hold the LCU tips flat and perpendicular on the glass surface at the entrance to the 16 mm diameter entrance port on the CheckMARC for three complete separate exposure cycles. Any user movements affecting the light measurements or significant differences between the three measurements were identified by the team at BlueLight Analytics by comparing the exposure time against the real-time irradiance data. Any abnormal results were rejected, and the measurement was repeated. The LCUs were generally tested using an exposure time of 10 or 20 seconds, with exceptions for some LCU modes that had shorter exposure times. The initial and the follow-up assessments of the LCUs were made in the same mode. When the representatives arrived at the dental office, they labelled each LCU with a unique sticker identification (I.D.) tag. At each visit, the I.D. tag, model, tip, and mode tested were entered into the CheckMARC database. Following the instructions provided by BlueLight Analytics, the representative examined and recorded the condition of each LCU tip to determine the presence of any visible material debris or damage. They then measured the irradiance three times using the standard output setting of each LCU and the dentist was informed on the condition and output from the LCU. The data collected were uploaded via the secure Amazon Web Services (AWS) cloud server for analysis. BlueLight Analytics personnel then filtered the collected data to select only the 1067 LCUs from the dental offices in United States and Canada that had been assessed twice between 2015 and 2021. The data was anonymized, and no personal information about the dentists or the dental offices was provided to the authors. Thus, the information used in this study contained only the brand of LCU, the presence of damage or debris on the LCU tip, the measured irradiances, the broad time range when the LCUs were reassessed, and whether the dental office was in the United States or Canada. Two consecutive assessments on the same LCU were defined as a pair, for a total of 2134 paired before and after assessments from 544 dental clinics (190 in Canada and 354 in the United States). The LCU output and the presence of damage and/or debris on the LCU tip were compared in each pair of assessments to determine if the issues with the LCU tip reported in the initial assessment had been resolved. In addition, the results from the 19 models of LCUs that had at least ten individual units tested twice were examined in greater detail. Five of these 19 models had 16 or more examples of that LCU.

The irradiance values recorded by these paired LCU assessments at the initial and their subsequent test were compared within each LCU using a paired t-test ($\alpha = 0.05$). A signed rank test was conducted at the same significance level when the data did not test positive for normality. Since multiple representatives from 3M carried out the testing, and at the request of the dental office staff, the time between each assessment was not fixed, and about 60% of the LCUs had been manufactured by 3M.

RESULTS

Of the 1067 initial assessments, 793 (74%) LCU tips had some damage, debris, or both *(Figure 1*). Out of these 1067 initial assessments, 34.8% had some damage to the tip, 29.1% had only debris on the tip, and 10.1% had both damage and debris on the tip. Therefore, nearly three-quarters of the lights tested in the participating dental offices in Canada and the United States were compromised and might not meet the manufacturer's specifications.

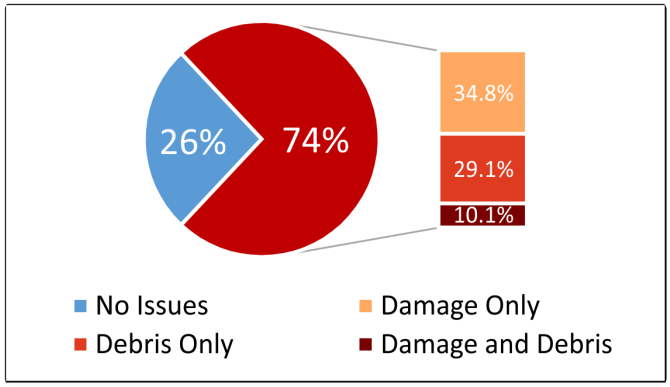

Figure 1: Condition (%) of the tip of the LCUs at the initial assessment (n = 1067 LCUs).

Figure 2 groups the observations where the tip damage or debris had been resolved as a function of the time interval between the initial and subsequent assessment. Due to the limitation of how the data was collected, 14.3% of these reassessments occurred within six months, 24.0% occurred within 6 to 12 months, 34.4% occurred within 12-to-24 months, and 27.3% occurred 25 to 36 months after the initial assessment. Overall, 65% of the LCU pairs had all their tip issues fully resolved between their first and second tests, but 35% of the LCU pairs still had some problems on the LCU tip that had not been rectified.

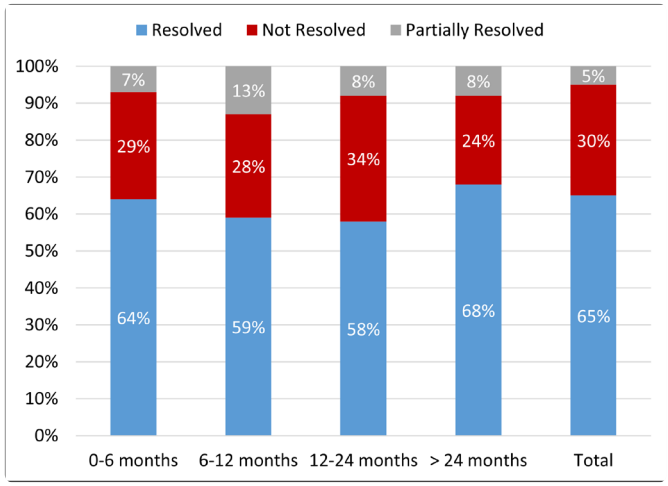

Figure 2: Percentage of all the LCUs tested that had their tip damage/debris issues resolved, grouped by the time interval between the two assessments (n = 2134 assessments, 1067 initial and 1067 subsequent assessments).

The irradiances from the LCUs ranged from 200 to 3,777 mW/cm^2. Figure 3 shows that 2.6% and 1.6% of the LCUs tested, delivered an irradiance below 500 mW/cm^2 in the first and second assessments, respectively. Most LCUs (about 61%) delivered an irradiance value between 1000 and 1499 mW/cm^2, and the overall percentage of LCUs in each irradiance range was similar at both assessment times *(Figure 3)*.

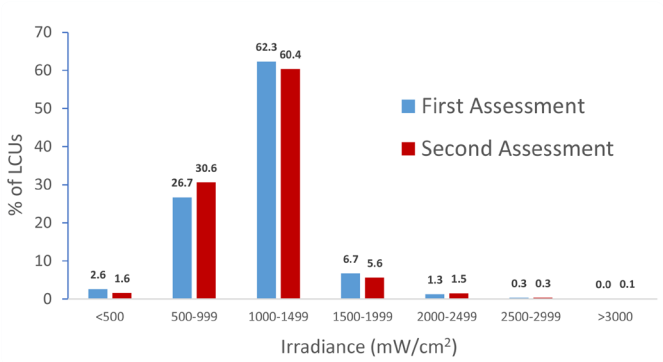

Figure 3: Distribution (%) of the paired LCUs within different irradiance ranges at the initial and second assessment (n = 1067 LCUs at each assessment).

Of the 868 LCUs that contained at least ten individual units of the same brand, 744 (86%) were single-peak LEDs, 114 (13%) were multi-peak LEDs, and 10 (11%) were PAC LCUs. The mean irradiance from the 19 most tested models (n=868) ranged from 649 mW/cm^2 to 1,625 mW/cm^2, with the minimum irradiance being 200 mW/cm^2 and a maximum of 2,152 mW/cm^2 *(Table 1)*. For these 19 models that had at least ten individual LCUs that had been retested, all but three models showed a decrease in irradiance on the second test *(Table 1)*. There was a large spread in output from LCUs of the same model. The variation within a given model for the before and after tests averaged 16% and 18.3%, respectively *(Table 1)*. The changes in irradiance between the first and second tests of the same LCU were significant ($p< 0.05$) for 10 of the 19 models of LCU. However, the changes were generally modest, with an average decrease in the irradiance of less than 5%. However, for three LCUs, the irradiance had fallen by more than 10% on the second test.

Figures 4A and 4B report the assessments of the five LCU brands that had a sample size of at least 16 LCUs with either damage to the tip or debris on the tip. The irradiance was higher when the debris or damage had been resolved and lower when it had not.

Of the 2134 initial and follow-up assessments, the LCU manufacturer provided an irradiance value for the output mode tested for 1910 (90%) of the LCUs. For 75.5% (n=1442) of these assessments, the irradiance was within ± 20% of the manufacturer's claimed value *(Figure 5)*. Forty-nine irradiance measurements were more than ± 50% of the manufacturer's stated value.

DISCUSSION

Most of the LCU pairs (74%) evaluated in this study had at least one problem with debris or damage on the tip at their first assessment *(Figure 1)*. In addition, 2.6% of the LCUs evaluated delivered an irradiance below 500 mW/cm^2 on the initial evaluation and 1.6% on the second assessment *(Figure 3)*. Of the 1910 tests of the LCUs for which the manufacturer provided an irradiance value, 468, or 24.5% of the tests deviated beyond ±20% of the manufacturer's claimed irradiance value *(Figure 5)*. Therefore, the first hypothesis that all the

Table 1. Minimum, maximum, and mean irradiance (Irr.) measured at the initial and subsequent assessment for the 19 LCU models (n=868) that contained at least ten individual units. 744 (86%) were single-peak LEDs, 114 (13%) were multi-peak LEDs, and 10 (11%) were PAC LCUs. The initial and subsequent results for each of these 19 LCU models were compared using a signed rank paired t-test (a = 0.05).

LCU Model	Source Type	Mode	n	Minimum Irr. (mW/cm²)	Maximum Irr. (mW/cm²)	Mean Irr. before (mW/cm²)	Mean Irr. after (mW/cm²)	Coeff. of Variation before/after	p-value	Irr. Difference	% Difference
Bluephase G2	Multi-peak LED	High	22	504	1306	1144	1082	10.4% / 17.5%	0.156	-62.00	-5.40%
Bluephase Style	Multi- peak LED	Std	33	279	1344	1024	989	18.3% / 22.6%	0.35	-35.58	-3.47%
Valo	Multi-peak LED	Std	39	660	1016	854	826	7.5% / 10.0%	0.006	-27.80	-3.26%
Valo Cordless	Multi-peak LED	Std	20	632	1085	881	879	13.9% / 14.2%	0.852	-2.70	-0.31%
Sapphire Supreme	PAC	Std	10	419	1880	1142	1000	32.2% / 35.7%	0.177	-141.80	-12.42%
Coltolux LED	Single-peak LED	Std	17	240	1128	733	649	26.1% / 24.7%	0.025	-83.70	-11.42%
Demi	Single-peak LED	Std	41	200	1840	1307	1239	21.6% / 21.2%	0.018	-68.00	-5.20%
Demi Plus	Single-peak LED	Std	104	458	1851	1243	1188	19.2% / 21.2%	0.004	-54.60	-4.39%
Demi Ultra	Single-peak LED	Std	15	921	1472	1199	1152	11.1% / 14.6%	0.147	-46.50	-3.88%
Elipar DeepCure-S	Single-peak LED	Std	75	877	1515	1339	1312	8.5% / 8.0%	0.003	-26.80	-2.00%
Elipar Freelightn2	Single-peak LED	Std	10	295	1076	779	801	25.6% / 34.7%	0.677	21.50	2.76%
Elipar S10	Single-peak LED	Std	310	291	1904	1060	1041	12.1% / 14.5%	<0.001	-18.50	-1.75%
Essentials	Single-peak LED	Std	14	872	1485	1204	1077	11.3% / 17.0%	0.011	-127.20	-10.56%
FlashLCU Magna 4.0	Single-peak LED	Std	10	1047	1960	1344	1360	15.5% / 18.9%	0.747	16.30	1.21%
Mini LED chair	Single-peak LED	Fast	20	859	1957	1571	1625	20.5% / 21.3%	0.072	54.10	3.44%
Ortholux Luminous	Single-peak LED	Std	17	1271	1758	1484	1442	8.6% / 9.8%	0.026	-41.50	-2.80%
Paradigm	Single-peak LED	Std	40	888	1425	1136	1105	8.1% / 10.5%	0.006	-30.60	-2.69%
Paradigm Deep Cure	Single-peak LED	Std	60	896	1545	1342	1319	8.0% / 8.2%	0.028	-23.00	-1.71%
Spec 3	Single-peak LED	Std	11	694	2152	1595	1470	24.9% / 23.5%	0.238	-124.50	-7.81%

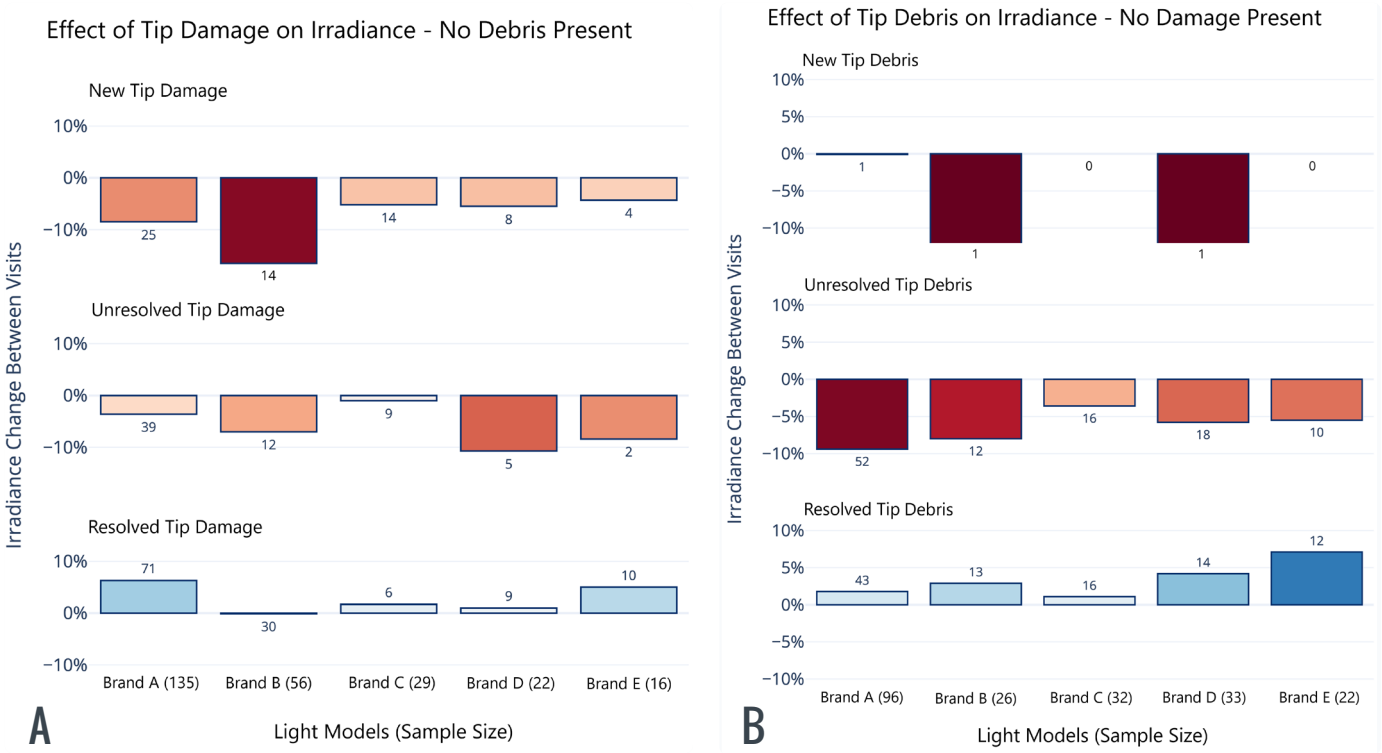

Figure 4A and 4B: Percent change in the irradiance for the five most popular LCUs (n≥16) when the tip damage (A) or debris (B) was or was not resolved by the time of the second assessment and when new tip damage was noted. The numbers represent the number of LCUs in each category.

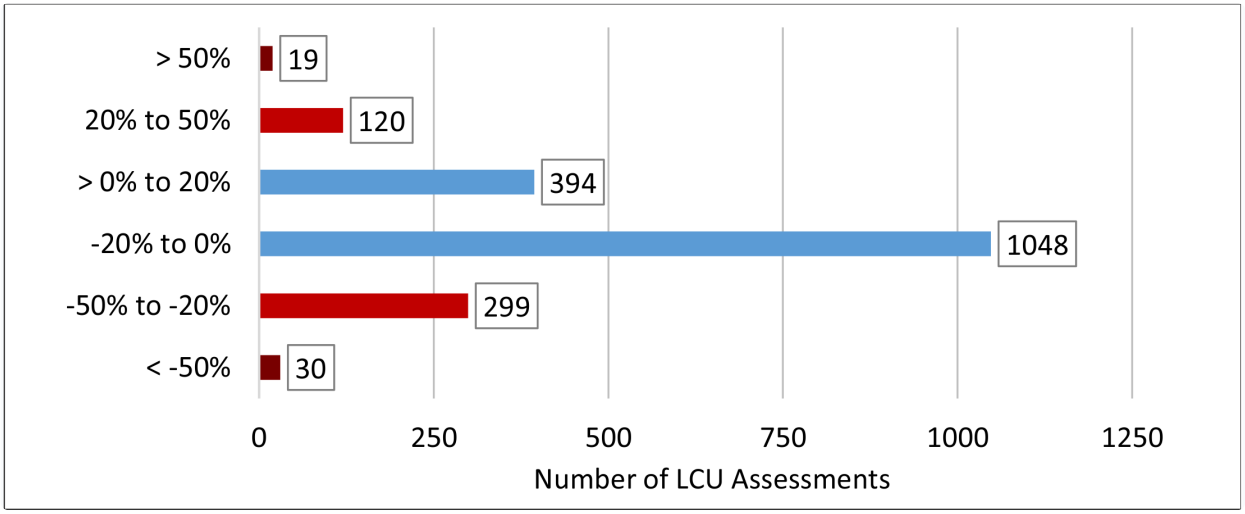

Figure 5: Number of LCU assessments separated into the amount (%) that the irradiance values deviated from the manufacturer's claimed irradiance (total n=1910 assessments because not all manufacturers provided an irradiance value for their LCU).

LCUs would be in good working order, that they would be free of tip damage and debris and compliant with the ISO 10650 standard, was rejected.

While it is encouraging that fewer LCUs emitted < 500 mW/cm^2 on their second assessment, 1.6% on the second assessment, this still means that 17 LCUs were being used on patients in the participating dental offices in US and Canada that delivered less than 500 mW/cm^2 (*Figure 3*). This is concerning. Unfortunately, despite office personnel being notified at the initial assessment about the deficiency in the LCUs they were using, some 35% of the LCUs still needed to have some tip issues resolved when they were retested (*Figures 2 and 4*). Thus, the second hypothesis that all problems would be resolved by the time of their retesting was rejected. However, it is encouraging to note that for the five brands of LCU with sample sizes of 16 or more, the irradiance was higher when any damage or debris on the tip was resolved, and lower when it had not been resolved (*Figure 4*).

Although the majority of the LCUs (~ 61%) delivered an irradiance value between 1,000 and 1,499 mW/cm^2 at both assessments (*Figure 3*), Table 1 shows that there was a wide range in the irradiance values (200 to 2,152 mW/cm^2) from the

19 LCU models that contained at least ten individual units (n= 868) and as high as 3,777 mW/cm^2 in the remaining LCUs. Of the 1910 light tests that had a manufacturer's stated irradiance value, 468, or 24.5% of the test results deviated beyond ±20% of the manufacturer's claimed irradiance value *(Figure 5)*. Since most dental offices do not carry out any maintenance procedures on their LCU, even if it was ten years old,[14] many dentists would be unaware that such a wide range in irradiance values existed or that the irradiance was dropping from their LCU.[13,59,60,62-66,73-75]

Since this study showed that 2.6% of the LCUs evaluated delivered an irradiance below 500 mW/cm^2 on the first and 1.6% on the second assessments *(Figure 3)*, if the operator used a 10 s exposure time, some dentists were delivering less than 5 J/cm^2 to photo-cure their RBCs. While this will produce a top surface that is hard, the bottom of the RBC will most likely be soft due to the 'off-label' use of this medical device.[57,58,76-79] The adverse effects of this 'under-curing' the resin are most likely to occur at the bottom of the proximal box because this region is the most challenging to illuminate[36-38] and less light is delivered to this region compared to the top surface.[35,37,39] Consequently, it is not surprising that this region is also where most clinical failures due to recurrent caries occur.[29,34]

A recent study[80] that examined 278 new LCUs from the same brand found that they were within – 4.3% and + 4.8 % of the output stated by the manufacturer (1,200 mW/cm^2) and thus well within the ISO 10650 standard when new. However, in the present study, the LCUs were being used in dental offices. Even within a single model of LCU, there was an average variance of about 15% in the irradiance values, and 33% of the assessments were outside of the ± 20% range stated by the manufacturers of the LCUs *(Figure 5)*. Since 74% of the 1067 LCUs initially examined had either some debris or some damage to their tip *(Figure 1)*, this may help to explain why there was such a wide range in irradiance values from the same brand of LCUs *(Table 1)*. The fact that there was a large spread in the irradiances from the matched pairs, from 200 to 3,777 mW/cm^2, and that the mean irradiance for each of these 19 popular brands ranged from 649 mW/cm^2 to 1625 mW/cm^2, is relevant because many dentists use the same exposure time independent of the brand, shade, and opacity of the RBC.[59,60] This means that resin restorations in the United States and Canada are receiving widely different amounts of energy (6.5 J/cm^2 to 16.3 J/cm^2 if the LCU is used for 10 s for the popular brands, and 2.0 J/cm^2 to 37.8 J/cm^2 from all the LCUs tested).

Manufacturers provide different instructions on the minimum irradiance, and the exposure time that should be used to photocure their RBCs.[57,58,76,77] For example, the instructions for Filtek One (3M) state that it should be photo-activated using 1000 mW/cm^2, or greater, for 20 s on the occlusal surface. Thus, 3M recommends that Filtek One receive at least 20 J/cm^2 to be considered adequately photocured.[79] Conversely, Ivoclar recommends that 2,700 – 3,300 mW/cm^2 delivered for 3 seconds (8.1 -9.9 J/cm^2) from the Bluephase PowerCure will be sufficient to photo-cure both Tetric PowerFlow and Tetric PowerFill.[57,77] Since the mean irradiance for the 19 most tested models ranged from 649 mW/cm^2 to 1,625 mW/cm^2, with the minimum irradiance being 200 mW/cm^2 and a maximum of 2,152 mW/cm^2, if a dentist used one of the more popular LCUs delivering 649 mW/cm^2 for only 10 s, they would deliver only 6.5 J/cm^2. This value is less than the radiant exposure recommended by the RBC manufacturers[57,58,76-79] and this will undoubtedly adversely affect the physical and chemical properties of the RBC.[5-18] These outcomes may contribute to increased secondary caries and the poor longevity of RBC restorations observed from private dental offices[26-29] compared to the good results from controlled clinical trials.[23,24] Nevertheless, it is encouraging that ~ 61% of the LCUs delivered an irradiance value between 1000 and 1499 mW/ cm^2, which means that in 10 s, these LCUs would provide between 10 and 15 J/cm^2, and this may be sufficient to photocure some,[57,77,78] but not all RBCs.[76,79] Of note, in the present study, the highest irradiance from one LCU was 3,777 mW/cm^2, meaning that the shortest possible exposure time for this LCU to deliver 10 J/cm^2 would be 3 s. No LCU could deliver 10 J/cm^2 in one second.

Despite claims that LEDs last for thousands of hours, all light sources degrade over time, and the cost of the LED emitter depends on how they are binned (sorted) based on their estimated lifespan before their output falls below 70% of their original value.[81] When assessed initially, most LCUs (74%) had at least one issue (damage or debris) with the tip of the LCU *(Figure 1)*. LEDs do not usually stop emitting light; instead, their light output gradually decreases. Thus, this study shows that it is critical that the user regularly monitors the output from the LCU to ensure that it continues to perform according to the manufacturer's specifications.[1-4] The light output and the LCU tip should be regularly inspected, and any damage or debris on the tip should be rectified before the LCU is used on patients. If the irradiance falls, then the dentist would know to increase the exposure time accordingly to compensate. If the irradiance falls below 20% of the manufacturer's stated output, then the LCU should be replaced because it would fall beyond the ISO 10650 standard of ± 20% and thus would not meet the manufacturer's specifications.

A limitation of this study was that the age of the LCUs is unknown and dental office sampling was biased. University clinics were not tested and only dental offices that wanted to have their LCUs tested at least twice were included. The measurements were made by multiple representatives from 3M and at different time intervals and this may account for some of the variance in the values. Also, the measured irradiance values were obtained by the representative holding the LCU in direct contact with the radiometer and thus were the radiant exitance (tip irradiance) values. This tip irradiance value does not necessarily represent the LCU's performance in a clinical situation where the bottom of the cavity in the proximal area is, on average, 6.3 mm[35] from the tip of the LCU. This distance can be even greater if the cavity is deeper, and sometimes, the matrix or matrix holder does not allow the tip to be positioned close

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to the RBC. These factors will all further reduce the irradiance received by the material.[36,37,43] The operator's skill can also significantly affect the outcome, and untrained operators may not deliver the minimum energy required to photo-cure the RBC adequately, even if the LCU has a high tip irradiance value.[82-88]

CONCLUSIONS

Within the limitations of this study, it can be concluded that many LCUs used on patients in private dental offices in the United States and Canada delivered light outputs that did not meet the manufacturer's specifications and did not meet the ISO 10650 standard. This was due to damage at the light tip, debris on the tip, or other factors. Specific conclusions are as follows:

1. There was a wide range in the irradiance values (200 to 3,777 mW/cm^2) from LCUs used in 544 dental offices in the United States and Canada. Approximately 61% delivered an irradiance between 1000 and 1499 mW/cm^2, and 2.6% of the initial 1067 individual LCUs tested delivered irradiance values below 500 mW/cm^2.
2. 24.5% of the irradiance assessments were outside ±20% of the irradiance claimed by the manufacturers of the LCUs.
3. When assessed initially, most LCUs (74%) had at least one issue (damage or debris) with the tip of the LCU.
4. When retested, 65% of the LCUs had all their tip damage and debris issues entirely resolved, but 35% of the LCUs still had some tip issues that needed to be resolved.

CLINICAL SIGNIFICANCE

LCUs are regulated medical devices. Their instructions for use require dental staff to regularly inspect to ensure they are free of damage and contamination and to verify the output. The wide range in irradiance values from the LCUs (200 to 3,777 mW/cm2) and the observation that only 65% of the LCUs were free of damage and contamination suggests that many LCUs used in dental offices have deficiencies that may affect the clinical longevity of dental restorations photo-cured with them.

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