

Intra- and inter-brand accuracy of four dental radiometers

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Abstract This study measured the accuracy and precision of four commercial dental radiometers. The intra-brand accuracy was also determined. The light outputs from 14 different curing lights were measured three times using four brands of dental radiometers and the results were compared to two laboratory-grade power meters that were used as the “gold standard”. To ensure proper representation, three examples of each brand of dental radiometer were used. Data collected was analyzed using ANOVA, with 95% confidence intervals, comparing the laboratory-grade meters to the dental radiometers. Bioequivalence was established where the confidence interval for the irradiance values was within $\pm 20\%$ of the “gold standard” reading. Forest plots were used to highlight bioequivalence values. The two laboratory-grade meters differed by less than 0.6%. Overall, all three examples of the Bluephase and SDI radiometers as well as two examples of the LEDRadiometer and one CureRite meter were bioequivalent to the gold standard. However, the type of curing light measured had a significant effect on the accuracy of the radiometer. There was significant variability of the irradiance read-

ings between radiometer brands, and between irradiance values recorded by the three samples of each brand studied. This made it impossible to definitively rank the radiometer brands for accuracy. Within the $\pm 20\%$ bioequivalence limits of this study, there was a clinically significant difference in the irradiance readings between radiometer brands and the choice of curing light affected the results. There was also significant variation in irradiance readings reported by different examples of the same brand of radiometer. Whether in clinical practice or in research, dental radiometers should not be used when either the irradiance or energy delivered needs to be accurately known.

Keywords Dentistry · Dental equipment · Lighting/instrumentation · Curing lights

Introduction

Light-cured resin composites are routinely used in dental offices as restorative materials and as luting agents [1]. Originally, quartz tungsten halogen (QTH) light-curing units (LCUs) were used to photopolymerize these materials, but now plasma arc (PAC) lights, lasers, and, recently, light-emitting diode (LED) units are also used. The durability of light-cured resin composite restorations and luting agents depends on adequate polymerization of the resin component within these products. However, the LCUs in many dental offices worldwide do not deliver an adequate light output [2–6]. The bulbs, LEDs, reflectors, and internal filters in dental LCUs have all been shown to degrade with use [7, 8]. In addition, autoclaving, disinfectant chemicals, or restorative material adhering to the tip of the LCU can all dramatically reduce the light output [9–11].

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Any of these factors may account for substandard polymerization of resins, especially if the user is unaware of the decline in light output.

Previous studies have reported that dental radiometers are unable to accurately measure the light output from dental LCUs. Shortall et al. showed that although relative irradiance values were attained according to the depth of cure of the resin, the absolute irradiance values reported by dental radiometers were not accurate [12]. In addition, Hansen and Asmussen reported that three handheld radiometers were unreliable in ranking 20 curing units on their ability to cure resin [13]. Another study by Rueggeberg et al. on the precision of radiometers found that the absolute irradiance values from two dental radiometers were significantly different [14].

Dental radiometers usually contain silicon photodiodes that convert light into electric current, then an analogue or digital meter displays the output from the curing light. Several factors may be responsible for the inaccuracy of dental radiometers. For example degradation of the radiometer over time and variability in the original calibration of the radiometer may affect the accuracy. Also, it has been reported that differences in the light guide tip diameter can significantly affect dental radiometer readings [15]. In addition, since LCUs deliver different spectral emissions, the type of bandpass filter used within these radiometers will affect the type of curing light (QTH, PAC, or LED) that used on that particular radiometer [16]. In particular measuring QTH curing lights with an LED-oriented radiometer has been reported to yield values higher than expected. This is of clinical concern because it may result in the operator believing that the output is higher and delivering insufficient energy to adequately cure the resin [16].

Despite the reports indicating that there are statistical differences between different radiometers, [13–16] these differences may not be clinically relevant because there is no universal standardization of the information that dental radiometers provide. Additionally, although general guidelines for assessing the substantial equivalence of medical/dental devices, e.g., 510(K), exist [17], no standard

methodology is specified by licensing agencies when determining equivalence of dental radiometers, as is the case for pharmaceutical bioequivalence [18]. Consequently, although many dental manufacturers, researchers and clinicians have used dental radiometers to measure the irradiance from curing lights [2, 3, 5, 6, 19–24], the actual irradiance delivered to the specimens may be in question.

The hypotheses of this study are:

1. That four popular brands of commercial dental radiometers will produce irradiance values that are bioequivalent to values from a laboratory-grade power meter;
2. That the accuracy of dental radiometers is the same between commercial brands; and
3. That there is no significant difference in irradiance values recorded by the same brand of radiometer.

Materials and methods

Table 1 and Fig. 1 show the four brands of dental radiometers and two laboratory-grade National Institute of Standards and Technology (NIST, Gaithersburg, MD, USA) referenced thermopiles (10-W PM-10, Coherent, Santa Clara, CA, USA) used in the study. The two thermopiles were used as the “gold standard” and for hypothesis 1; the irradiance results reported by the dental radiometers were compared to the results from this gold standard. To test hypothesis 2, readings from the four different brands of radiometer were compared for inter-brand variability. To test hypothesis 3, the results from the three examples of each brand of radiometer were compared for intra-brand variability.

Table 2 lists the 14 different LCUs that were measured in random order by the radiometers. The LCUs tested varied from a broad spectrum plasma arc curing light and halogen curing light, to single-peak and polywave™ LED units. The exit apertures at the end of the curing lights were often larger than the diameter of the dental radiometer sensor window. To calculate irradiance from the power values (in

Table 1 Manufacturers and serial numbers of the radiometers

Radiometer model	CureRite serial number	Bluephase serial number	LEDRadiometer serial number	SDI serial number	Gold Standard PM-10 serial number
Manufacturer	Dentsply Inc. York, PA	Ivoclar-Vivadent Inc. Amherst, NY	Kerr Corp Demetron Kerr Corp., Orange, CA	SDI N. America Bensenville, IL	Coherent Inc., Santa Clara, CA
Radiometer #1	7123	49	79302023	21210	1279K05
Radiometer #2	5615	32	79306793	21213	0679A08R
Radiometer #3	7614	1431	79306792	21209	N/A

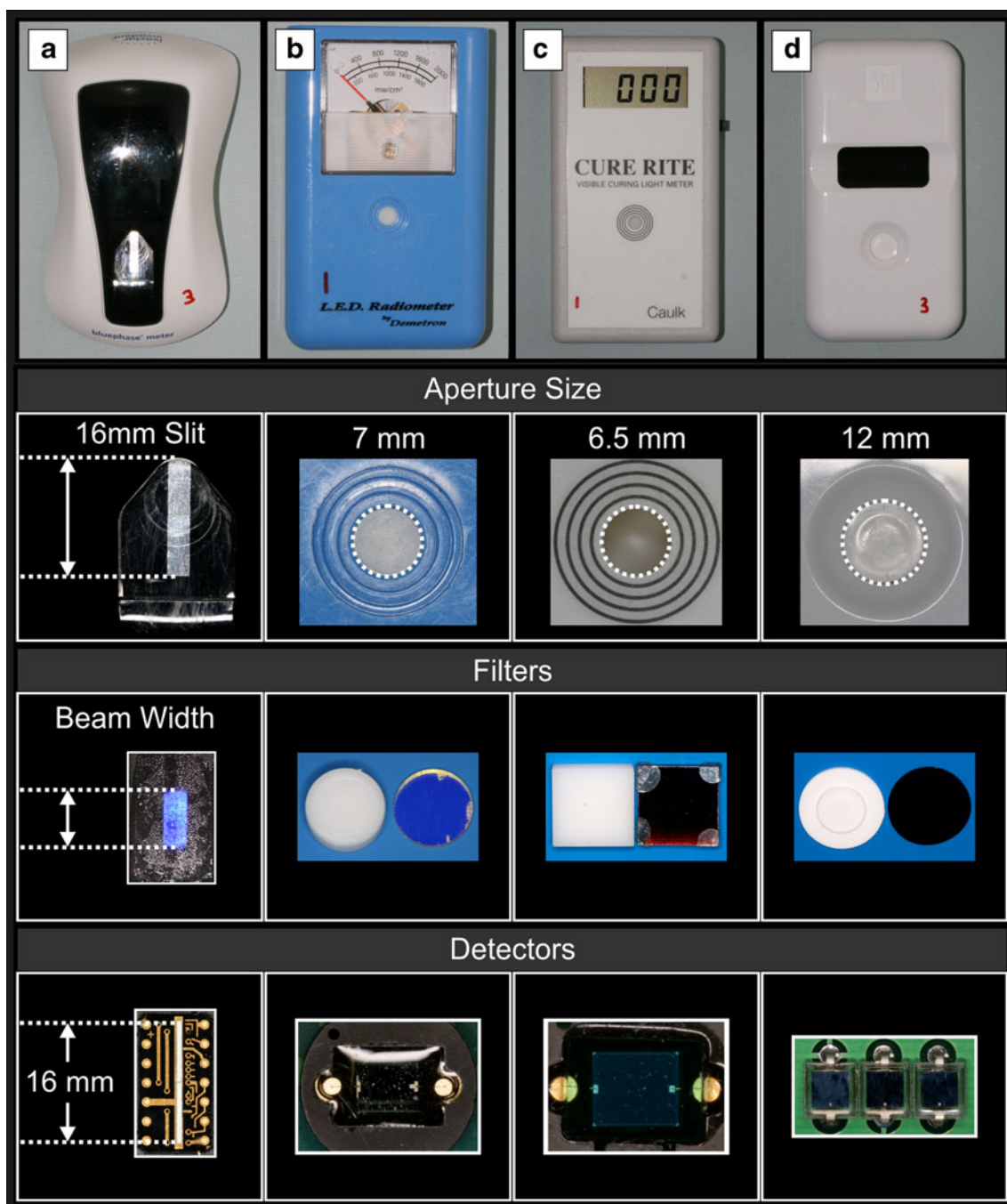


Fig. 1 Brands of the four dental radiometers used in this study and their respective aperture size, bandpass filters, and light detectors. **a** Bluephase, **b** LEDRadiometer, **c** CureRite, **d** SDI Radiometer. The detector on the Bluephase is a slit shape and a different configuration

milliwatts) measured using the thermopiles, the internal diameter of the light tip was measured using $\times 2.5$ magnification. The power output obtained from the thermopile was divided into the area of the light-emitting tip to obtain the average irradiance (milliwatts per square centimeter). The spectral emissions from the LCUs shown in Figs. 2 and 3 were measured with a laboratory-grade USB 4000 spectroradiometer (Ocean Optics, Dunedin, FL, USA) connected to a 6-in. integrating sphere (Labsphere, North

Sutton, NH, USA) that had an internal NIST referenced 35-W calibration lamp.

The irradiance results from the PM#1 and PM#2 meters were compared; accuracy was inferred if these two NIST referenced meters gave similar readings. Each light was positioned with the end tip of the light guide parallel to and 1 mm from the surface of the thermopile sensor. The Field Max II TO (Coherent) meters reported the mean power during the last 5 s of a 10-s curing cycle. To record the

Table 2 Curing light types, (light-emitting diode: LED, quartz tungsten halogen: QTH, plasma arc: PAC) and manufacturers

Curing lights and type (LED, QTH, PAC)	Light guide	Internal diameter of light guide (mm)
FlashLite Magna (LED) Discus Dental, Culver City, CA	None	
Allegro (LED) Den-Mat Holdings, Santa Maria, CA	8 mm Turbo	7.1
Bluephase 16i (LED) Ivoclar-Vivadent Inc., Amherst, NY	13/8 mm Turbo	7.3
LEDemetron II (LED) Kerr Corp., Orange, CA	13/8 mm Turbo	7.1
FreeLight 2 (LED) 3 m ESPE, St. Paul, MN	9/8 mm Turbo	7.6
SmartLite iQ (LED) Dentsply Inc., York, PA	13/8.5 mm Turbo	8.2
SmartLite IQ 2 (LED) Dentsply Inc., York, PA	12/8 mm Turbo	8.2
Radii Plus (LED) SDI, N. America, Bensenville, IL	None	
OptiCure (Polywave LED) Designs for Vision, Ronkonkoma, NY	13/10 mm Turbo	9.9
Bluephase G2 (Polywave LED) Ivoclar-Vivadent Inc., Amherst, NY	10 mm standard	9.0
G-Light (Polywave LED) GC America, Alsip, IL	11/7 mm Turbo	6.8
DEMI (LED) Kerr Corp., Orange, CA	13/8 mm Turbo	7.2
Optilux 501 (QTH) Kerr Corp., Orange, CA	13/8 mm Turbo+	7.1
Sapphire (PAC) Den-Mat Holdings, Santa Maria, CA	5.4 mm to 8.4 mm Reverse Turbo	8.4

output of the curing lights on the dental radiometers, the tip of the light guide was positioned flush on a non-sensor surface area of the radiometer for the first 5 s. In a horizontal sliding motion, the tip of the light guide was moved to cover the radiometer sensor for the last 5 s. The maximum radiometer reading obtained with the tip of the curing light in contact with the dental radiometer sensor window was recorded. The battery-operated curing lights were fully charged before their outputs were tested. Each curing light was used for 20 s prior to being measured so that the light source could warm up and the light output would stabilize [24].

To ensure proper representation of each brand of dental radiometer, three examples of each brand of meter were used. The experiment was repeated three times on different days and the lights and meters were used in a random order for each trial. Data collected was analyzed using analysis of variance, with 95% confidence intervals (C.I.), comparing the results

from the gold standard thermopiles to those from the dental radiometers. Bioequivalence was established if the confidence interval for the irradiance values were within $\pm 20\%$ of the gold standard thermopile reading [25]. Forest plots were used to highlight the bioequivalence results [26].

Results

On average, when measuring the 14 different lights, the irradiance values from the two laboratory-grade meters differed by less than 0.6%: 1,142.7 vs. 1,148.8 mW/cm², with an average difference of -6.05 [95% confidence interval: $-9.09, -3.01$ mW/cm²]. Thus, the results obtained from the two laboratory-grade meters were combined and the mean irradiance value was reported in Table 3.

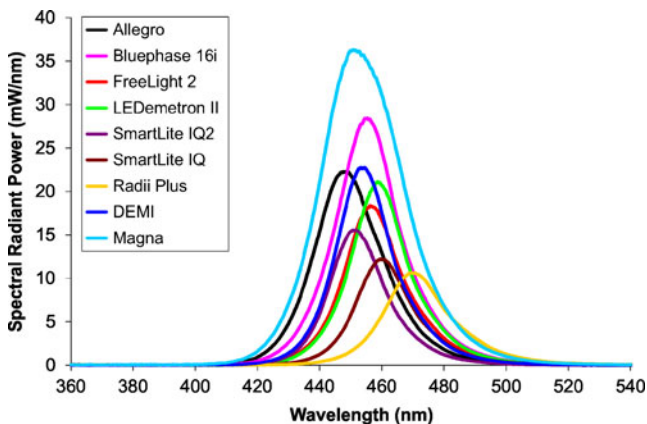
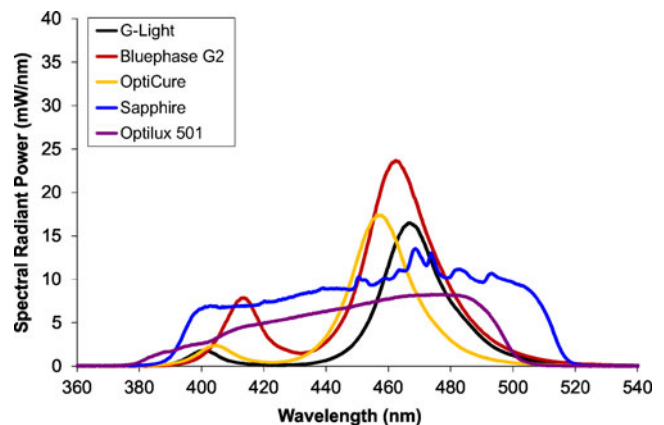
**Fig. 2** Spectral distribution of single-peak LED curing lights**Fig. 3** Spectral distribution of the polywave™ LED curing lights (G-Light, Bluephase G2, and OptiCure), QTH curing light (Optilux 501) and PAC curing light

Table 3 Irradiance results from 14 curing lights measured using four dental radiometers compared to the single mean irradiance value measured from two laboratory-grade meters (PM-10 thermopile)

	PM-10	S.D	Bluephase	S.D	LEDRadiometer	S.D	CureRite	S.D	SDI	S.D
Meter 1										
Sapphire	2,254	45	2,620	89	1,400	100	1,916	31	1,223	28
Bluephase 16i	1,639	6	1,670	44	1,250	50	2,000	0	1,645	35
Allegro	1,431	15	1,666	32	1,050	0	1,699	8	1,238	12
LEDemetron II	1,396	13	1,350	26	1,050	50	1,908	12	1,547	8
DEMI	1,394	22	1,463	31	1,117	29	1,931	16	1,590	18
Bluephase G2	1,282	11	1,240	10	1,050	0	1,430	7	1,133	15
Magna	1,133	9	913	12	983	29	1,621	19	1,658	37
G-Light	1,131	25	1,073	21	800	0	1,088	8	773	6
Radii Plus	973	51	340	26	600	0	1,593	25	1,527	24
FreeLight 2	909	3	1,010	26	758	14	1,199	28	988	8
Optilux 501	716	9	930	92	650	0	1,045	35	665	9
SmartLite IQ2	644	2	737	6	600	0	886	6	750	18
OptiCure	589	10	723	21	658	14	1,095	11	933	28
SmartLite IQ	529	11	960	17	550	0	823	2	648	6
Meter 2										
Sapphire	2,254	45	2,360	279	1,533	14	2,000	0	1,232	8
Bluephase 16i	1,639	6	1,600	10	1,500	0	2,000	0	1,652	8
Allegro	1,431	15	1,450	46	1,200	0	1,794	47	1,197	12
LEDemetron II	1,396	13	1,210	46	1,392	72	2,000	0	1,503	35
DEMI	1,394	22	1,360	10	1,367	14	2,000	0	1,542	23
Bluephase G2	1,282	11	1,200	20	1,200	0	1,541	8	1,132	13
Magna	1,133	9	803	29	1,017	29	1,623	9	1,618	43
G-Light	1,131	25	970	10	892	14	1,175	12	760	18
Radii Plus	973	51	287	6	617	14	1,708	7	1,453	15
FreeLight 2	909	3	627	465	900	0	1,306	8	977	33
Optilux 501	716	9	793	12	792	14	1,181	7	668	8
SmartLite IQ2	644	2	563	21	692	14	954	9	741	4
OptiCure	589	10	690	0	733	14	1,181	10	940	5
SmartLite IQ	529	11	773	12	650	0	899	13	653	10
Meter 3										
Sapphire	2,254	45	2,303	55	1,542	14	1,908	14	1,241	12
Bluephase 16i	1,639	6	1,737	50	1,442	14	1,493	19	1,591	10
Allegro	1,431	15	1,483	42	1,192	14	1,138	4	1,158	9
LEDemetron II	1,396	13	1,333	25	1,358	14	1,372	16	1,493	11
DEMI	1,394	22	1,553	21	1,400	25	1,447	28	1,497	8
Bluephase G2	1,282	11	1,270	26	1,167	14	1,190	9	1,108	10
Magna	1,133	9	877	6	1,000	0	1,168	23	1,532	10
G-Light	1,131	25	1,093	49	883	14	963	7	763	3
Radii Plus	973	51	353	81	650	0	1,509	13	1,461	5
FreeLight 2	909	3	1,023	55	892	14	866	6	955	5
Optilux 501	716	9	907	32	767	14	857	6	647	8
SmartLite IQ2	644	2	690	10	700	0	599	8	715	5
OptiCure	589	10	667	6	767	14	792	8	908	7
SmartLite IQ	529	11	927	21	650	0	637	6	625	9

Table 4 Bioequivalence results of the dental radiometers tested using all 14 lights

Meter	Estimate type	RMS proportion	Mean	Lower CI limit	Upper CI limit	Std error
Bluephase #1	Within $\pm 20\%$	5.2%	-44.4	-124.4	35.6	39.6
Bluephase #2	Within $\pm 20\%$	8.4%	89.4	15.9	162.8	36.4
Bluephase #3	<i>Within $\pm 10\%$</i>	3.2%	<i>-10.2</i>	<i>-82.0</i>	<i>61.7</i>	35.6
CureRite #1	Within $\pm 40\%$	26.1%	-297.1	-374.6	-219.5	38.4
CureRite #2	Within $\pm 40\%$	33.1%	-377.7	-454.7	-300.7	38.1
CureRite #3	<i>Within $\pm 10\%$</i>	3.0%	9.8	-57.4	77.0	33.3
LEDRadiometer #1	Within $\pm 30\%$	22.4%	254.1	182.0	326.3	35.7
LEDRadiometer #2	Within $\pm 20\%$	9.6%	104.1	35.4	172.9	34.1
LEDRadiometer #3	Within $\pm 20\%$	10.8%	119.0	49.2	188.8	34.6
SDI #1	Within $\pm 20\%$	5.4%	-17.5	-138.5	103.5	59.9
SDI #2	Within $\pm 20\%$	5.1%	0.4	-116.8	117.6	58.0
SDI #3	Within $\pm 20\%$	5.5%	27.1	-86.5	140.8	56.3

Units within $\pm 10\%$ are presented in italics

Table 4 and the Forest plots in Fig. 4 show the average irradiance values produced from all the radiometers compared to the gold standard laboratory-grade power meters. Overall nine radiometers passed the $\pm 20\%$ bioequivalence standard. The CureRite meter #3 followed by the Bluephase meter #3 recorded the irradiance values closest to the gold standard and passed a $\pm 10\%$ bioequivalence standard. In sharp contrast, CureRite meter #1 and CureRite meter #2 performed poorly and were not bioequivalent. Although the irradiance reported by the SDI meter #2 was on average the closest to the gold standard, Table 4 shows that the confidence interval for this meter was wider, indicating less precision in the irradiance values from this radiometer. To account for different types of radiometers potentially responding better to different categories of dental curing light, radiometer ability was analyzed separately using the

results just from the single-peak LED, polywave™ LED, QTH, and PAC curing lights.

The performance of dental radiometers with single-peak LED lights is shown in Fig. 5 and Table 5. Here, eight of the radiometers passed the $\pm 20\%$ bioequivalence standard and the CureRite #3 passed a $\pm 10\%$ bioequivalence standard. The CureRite meter #3 and Bluephase meters #1 and #3 were the best, but the CureRite meters #1 and #2 performed poorly and were not bioequivalent. The ability of radiometers to measure polywave™ LED lights is shown in Fig. 6 and Table 6. The Bluephase meters #1 and #3 tested as most accurate and the most precise. These two meters passed a $\pm 10\%$ bioequivalence standard. Although the CureRite #3 passed the $\pm 20\%$ bioequivalence standard, it was slightly less accurate and less precise having a wider confidence interval than the Bluephase meters #1 and #3. In general, the confidence intervals for polywave™ measurements were

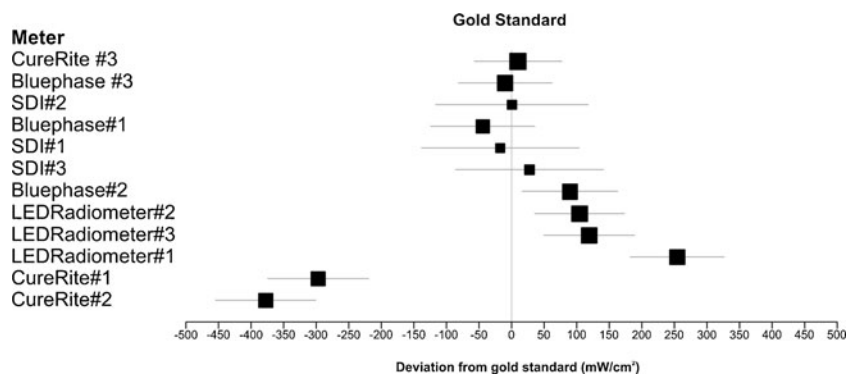


Fig. 4 Comparison of mean irradiance values from the dental radiometers measuring all of the lights. Vertical line in the center of the graph indicates an average of the laboratory-grade meter values. Square points indicate mean irradiance values, lines indicate lower to upper 95% confidence limits for the mean. CureRite meter #3 and Bluephase #3 performed best at $\pm 10\%$ bioequivalence [C.I. -57.4,

77.0 mW/cm², and C.I. -82.0, 61.7 mW/cm², respectively] and CureRite meters #1 and #2 performed the worst at $\pm 40\%$ bioequivalence [C.I. -374.6, -219.5 mW/cm² and C.I. -454.7, -300.7 mW/cm², respectively]. SDI meter #2 had the closest readings to the thermopile, but had a large confidence interval [C.I. -116.8, 117.6 mW/cm²] indicating less precision

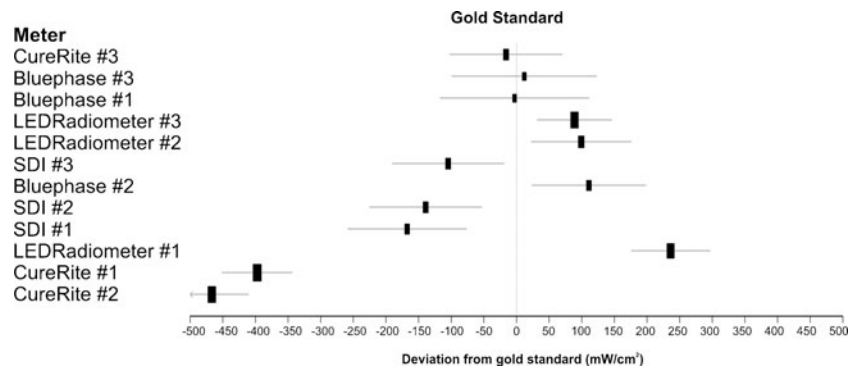


Fig. 5 Comparison of mean irradiance values from the dental radiometers tested with single-peak LED curing lights. *Vertical line* in the center of the graph indicates an average of the laboratory-grade meter values. *Square points* indicate mean irradiance values, *lines* indicate lower to upper 95% confidence limits for the mean. The majority of lights passed the $\pm 20\%$ bioequivalence standard. CureRite meter #3

performed best at $\pm 10\%$ bioequivalence [C.I. $-102.3, 70.2 \text{ mW/cm}^2$], Bluephase meters #1 and #3 were at $\pm 20\%$ bioequivalence [C.I. $-117.3, 111.36 \text{ mW/cm}^2$ and C.I. $-99.2, 122.8 \text{ mW/cm}^2$, respectively]. CureRite meters #1 and #2 performed most poorly at $\pm 40\%$ [C.I. $-451.1, -343.7 \text{ mW/cm}^2$] and $\pm 50\%$ [C.I. $-523.1, -410.6 \text{ mW/cm}^2$] bioequivalence, respectively

very wide and thus very imprecise. Although six meters passed the $\pm 20\%$ bioequivalence standard, most radiometers were imprecise and thus unreliable. CureRite meters # 1 and #2 were not bioequivalent and were the least accurate meters.

Discussion

In this study, there was a bioequivalent difference between the irradiance values reported by the four brands of dental radiometers and the gold standard laboratory-grade power meters. As a group, the meters failed to meet the $\pm 20\%$ bioequivalence standard we used, thus hypothesis 1 was rejected. However, individually, the three examples of the Bluephase and SDI radiometers as well as two examples of the LEDRadiometer and one CureRite meter passed the $\pm 20\%$ bioequivalence standard. Hypothesis 2 was rejected, as there was a significant variability of the irradiance readings between brands. Finally, hypothesis 3 was rejected as there was a significant variation between irradiance values found in the three samples of each brand studied, making it impossible to definitively rank brands for accuracy.

The ability of the radiometers to measure QTH units is shown in Fig. 7 and Table 7. Eight radiometers passed the $\pm 20\%$ bioequivalence standard. The LEDRadiometer #3 and SDI meters # 1 and #2 measured closest to the gold standard. CureRite meters #1 and #2 were again the least accurate radiometers, and together with Bluephase meter #1 had a very wide confidence interval. This indicated a lack of precision when measuring QTH curing lights.

The ability of the radiometers to measure the PAC unit is shown in Fig. 8 and Table 8. The Bluephase meter #3 was the only radiometer that passed the $\pm 20\%$ bioequivalence standard. All the other radiometers gave highly inaccurate and imprecise readings.

Table 5 Bioequivalence results of the dental radiometers tested using the single-peak LED lights

Meter	Estimate Type	RMS Proportion	Mean	Lower CI limit	Upper CI limit	Std Error
Bluephase #1	Within $\pm 20\%$	4.9%	-3.0	-117.3	111.4	55.6
Bluephase #2	Within $\pm 20\%$	10.4%	110.9	23.6	198.2	42.5
Bluephase #3	Within $\pm 20\%$	4.8%	11.8	-99.2	122.8	54.0
CureRite #1	Within $\pm 40\%$	34.8%	-397.4	-451.1	-343.7	26.1
CureRite #2	Within $\pm 50\%$	40.8%	-466.9	-523.1	-410.6	27.4
CureRite #3	<i>Within $\pm 10\%$</i>	3.9%	<i>-16.1</i>	<i>-102.3</i>	<i>70.2</i>	42.0
LEDRadiometer #1	Within $\pm 30\%$	20.8%	236.1	175.6	296.5	29.4
LEDRadiometer #2	Within $\pm 20\%$	9.2%	99.0	22.4	175.7	37.3
LEDRadiometer #3	Within $\pm 20\%$	8.1%	88.9	31.9	145.8	27.7
SDI #1	Within $\pm 30\%$	15.1%	-167.6	-258.3	-76.9	44.1
SDI #2	Within $\pm 20\%$	12.7%	-139.3	-225.2	-53.4	41.8
SDI #3	Within $\pm 20\%$	9.8%	-104.8	-190.7	-19.0	41.8

Units within $\pm 10\%$ are presented in italics

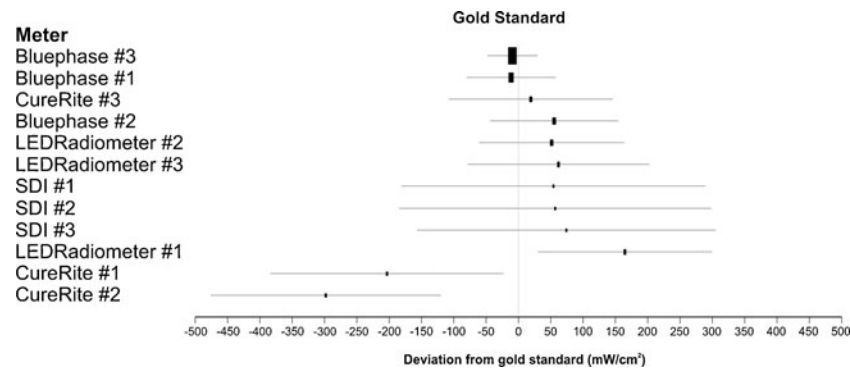


Fig. 6 Comparison of mean irradiance values from the dental radiometers tested with polywave™ LED curing lights. *Vertical line* in the center of the graph indicates an average of the laboratory-grade meter values. *Square points* indicate mean irradiance values, *lines* indicate lower to upper 95% confidence limits for the mean. Although the majority of lights tested passed the $\pm 20\%$ bioequivalence standard, the large confidence intervals involved render these

readings highly imprecise. Bluephase meters #1 and #3 performed best at $\pm 10\%$ bioequivalence [C.I. $-80.0, 57.0 \text{ mW/cm}^2$ and C.I. $-47.9, 29.3 \text{ mW/cm}^2$, respectively]; CureRite meter #3 was $\pm 20\%$ bioequivalence [C.I. $-107.6, 145.7 \text{ mW/cm}^2$]. CureRite meter #1 and #2 performed poorest at $\pm 40\%$ [C.I. $-383.6, -23.4 \text{ mW/cm}^2$] and $\pm 50\%$ [C.I. $-476, -120 \text{ mW/cm}^2$] bioequivalence, respectively

Equivalence testing was possible because the readings from the two laboratory meters differed by less than 0.5%, with an average difference of 6 mW/cm^2 (95% CI $-9, -3 \text{ mW/cm}^2$). Instead of using statistically significant differences that are often quoted as $p < 0.05$, this study used a 95% confidence interval for the mean irradiance values lying within $\pm 20\%$ of the gold standard (laboratory meters) as the equivalence standard. This standard is analogous to the method for comparing the pharmacokinetic parameter between a generic drug seeking approval and its brand-name counterpart. The American Food and Drug Administration considers two products bioequivalent if the 90% confidence intervals (90% CI) of the results obtained using a generic formulation are within 80.00% to 125.00% of the reference formulation [18]. Although other metrics are possible, this one is used widely in other areas and may be more clinically relevant [25]. Table 4

and Fig. 4 show that measuring all the lights, overall, all three examples of the Bluephase and SDI radiometers were found to be $\pm 20\%$ bioequivalent to the gold standard, as well as LEDRadiometer #2 and #3, and CureRite meter #3. In fact, CureRite meter #3 met a more stringent bioequivalence standard of $\pm 10\%$. Table 5 and Fig. 5 show that when tested with single-peak LED units, again, all the Bluephase radiometers were bioequivalent, as were LEDRadiometer #2 and #3 as well as the SDI #2 and 3 meters. The CureRite meter #3 was bioequivalent at $\pm 10\%$. As anticipated, all the Bluephase radiometers were bioequivalent when tested on the polywave™ LED units, as were the LEDRadiometer #2 and #3, and the CureRite meter #3. In particular, the Bluephase meters #1 and #3 were the most accurate at $\pm 10\%$ bioequivalence when testing the polywave™ LED units. As shown in Fig. 7 and Table 7, when tested on the QTH units, the LEDRadi-

Table 6 Bioequivalence results of the dental radiometers tested using the polywave LED curing lights

Meter	Estimate Type	RMS Proportion	Mean	Lower CI limit	Upper CI limit	Std Error
Bluephase #1	<i>Within $\pm 10\%$</i>	2.8%	-11.5	-80.0	57.0	29.7
Bluephase #2	Within $\pm 20\%$	6.1%	55.2	-43.7	154.0	42.9
Bluephase #3	<i>Within $\pm 10\%$</i>	1.7%	-9.3	-47.9	29.3	16.7
CureRite #1	Within $\pm 40\%$	19.0%	-203.5	-383.6	-23.4	78.1
CureRite #2	Within $\pm 50\%$	26.9%	-298.2	-476	-120.4	77.1
CureRite #3	Within $\pm 20\%$	5.1%	19.1	-107.6	145.7	54.9
LEDRadiometer #1	Within $\pm 30\%$	15.2%	164.6	30.2	299.1	58.3
LEDRadiometer #2	Within $\pm 20\%$	6.2%	51.3	-60.9	163.5	48.7
LEDRadiometer #3	Within $\pm 20\%$	7.6%	61.8	-78.3	201.9	60.8
SDI #1	Within $\pm 30\%$	10.1%	54.1	-180.9	289.0	101.9
SDI #2	Within $\pm 30\%$	10.4%	56.8	-184.2	297.9	104.5
SDI #3	Within $\pm 30\%$	10.9%	74.1	-156.8	304.9	100.1

Units within $\pm 10\%$ are presented in italics

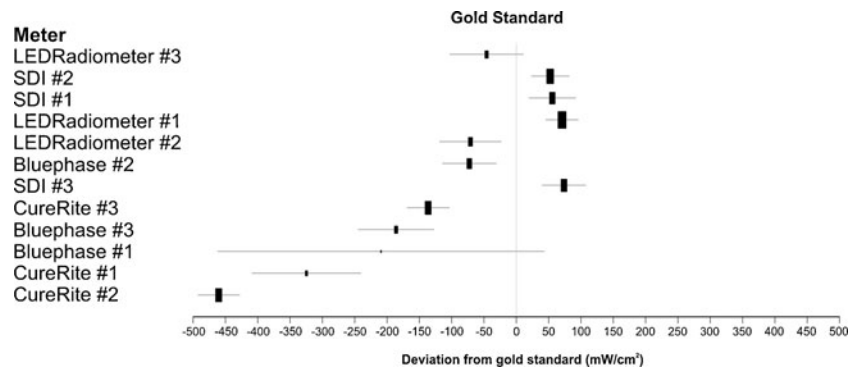


Fig. 7 Comparison of mean irradiance values from the dental radiometers tested with a halogen curing light. Vertical line in the center of the graph indicates an average of the laboratory-grade meter values. Square points indicate mean irradiance values, lines indicate lower to upper 95% confidence limits for the mean. Most radiometers passed the $\pm 20\%$ bioequivalence. LEDemtron meter #3 [C.I. -476.0 ,

-120.0 mW/cm^2] and SDI meter # 1 and #2 measured at $\pm 10\%$ bioequivalence [C.I. 19.5, 91.7 mW/cm^2 and C.I. 22.9, 81.6 mW/cm^2 respectively]. CureRite meter #1 and #2 were the least accurate [C.I. -409.1 , -240.2 mW/cm^2 and C.I. -492.7 , -428.1 mW/cm^2 respectively], and Bluephase meter #1 also had a very wide, inaccurate confidence interval [C.I. -462.1 , 43.3 mW/cm^2]

ometer and SDI radiometers along with the Bluephase meter #2 and CureRite #3 passed the $\pm 20\%$ bioequivalence standard. Overall, the radiometers had the best results when tested on the QTH units with six of the radiometers meeting a $\pm 10\%$ standard of bioequivalence. Table 8 and Fig. 8 show readings taken from the PAC unit were generally beyond the limits of the Forest plot and were thus both highly inaccurate and imprecise with only the Bluephase meter #3 meeting the $\pm 20\%$ bioequivalence standard.

The different LCUs tested in this study represent the range of QTH, LED, and PAC units commonly used in dental offices. Figures 2 and 3 show that there is a wide range in the spectral emission from the LCUs used in this study. Figure 1 illustrates the different designs of dental radiometers used in this study and it was expected that the company’s corresponding brand of radiometer would function most accurately with their own brand of light [14, 15]. For

instance, Ivoclar-Vivadent manufactures both single-peak and polywave™ curing lights and, as expected, the Ivoclar-Vivadent Bluephase radiometers performed best, with these lights meeting the $\pm 20\%$ bioequivalence standard. However, the other brands of radiometer did not function as expected. The Dentsply CureRite radiometers were designed for QTH units [27], but they performed the most poorly on the QTH light. SDI & Kerr make single-peak type LED curing lights, but in this study the SDI & Kerr radiometers [28, 29] gave the most accurate readings for the QTH unit, and were least accurate when measuring single-peak LED curing lights.

This study found a wide variation in the results from the three radiometer samples within the same brand, making it impossible to definitively rank brands for accuracy. Overall, testing the 14 curing lights, the CureRite #1 and #2 radiometers were the least accurate radiometers, but the CureRite meter #3 performed best overall. This illustrates the large

Table 7 Bioequivalence results of dental radiometers tested with the QTH light

Meter	Estimate Type	RMS Proportion	Mean	Lower CI limit	Upper CI limit	Std. Error
Bluephase #1	Within $\pm 50\%$	19.0%	-209.4	-462.1	43.3	58.7
Bluephase #2	Within $\pm 10\%$	6.4%	-72.7	-114.4	-31.1	9.7
Bluephase #3	Within $\pm 30\%$	16.3%	-186.1	-244.8	-127.3	13.7
CureRite #1	Within $\pm 40\%$	28.4%	-324.7	-409.1	-240.4	19.6
CureRite #2	Within $\pm 50\%$	40.2%	-460.4	-492.7	-428.1	7.5
CureRite #3	Within $\pm 20\%$	11.9%	-136.4	-169.3	-103.5	7.7
LEDRadiometer #1	Within $\pm 10\%$	6.2%	70.6	45.6	95.6	5.8
LEDRadiometer #2	Within $\pm 20\%$	6.3%	-71.1	-118.7	-23.4	11.1
LEDRadiometer #3	Within $\pm 10\%$	4.2%	-46.1	-103.1	11.0	13.3
SDI #1	Within $\pm 10\%$	4.9%	55.6	19.5	91.7	8.4
SDI #2	Within $\pm 10\%$	4.6%	52.3	22.9	81.6	6.8
SDI #3	Within $\pm 10\%$	6.5%	73.6	39.7	107.5	7.9

Units within $\pm 10\%$ are presented in italics

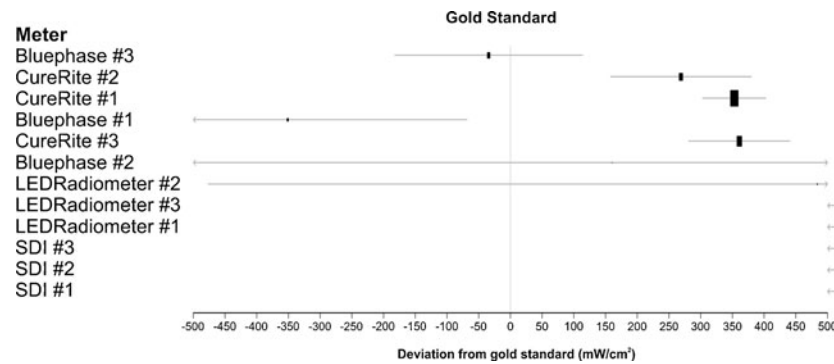


Fig. 8 Comparison of mean irradiance values from the dental radiometers tested with a plasma arc curing light. Vertical line in the center of the graph indicates a confidence limit of the laboratory-grade meter. Square points indicate mean irradiance values, lines indicate

lower to upper 95% confidence limits for the mean. Bluephase meter #3 was the most accurate radiometer, at 20% bioequivalence [C.I. -182.7, 113.8 mW/cm²]. All other meters gave highly inaccurate readings with five of the radiometers off the chart

variation that can occur within the same brand of dental radiometer. The time when each sample was manufactured may explain some of these differences (Table 1). For instance, serial numbers from the Bluephase meters #1 and #2 (serial #49, 32) suggest that these meters were manufactured at a different time period than the Bluephase meter #3 (serial #1431) and Bluephase #3 was a more accurate meter achieving a $\pm 10\%$ bioequivalence standard. The same inconsistency within a brand of radiometer is seen in CureRite meters #1, #2, and #3, but here the serial numbers appear to be unrelated to radiometer performance. Although meters #1 and #3 have relatively similar serial numbers (serial #7213, 7614) compared to meter #2 (serial #5615), the CureRite meter #3 was more accurate achieving a $\pm 10\%$ bioequivalence standard compared to meters #1 or #2.

None of these dental radiometers could be relied upon to accurately report the irradiance from a range of dental LCUs and thus should not be used in research studies that require the irradiance or energy delivered to the specimens to be known.

Clinicians should not try to compare the irradiance values from different curing lights using dental radiometers because the results may or may not be accurate. Additionally, the different brands of dental radiometers cannot be relied upon to always provide a higher or lower irradiance value than the gold standard. However, dental radiometers such as those used in this study can be useful in dental offices as a means to measure the change in the irradiance from a single light over time. Future studies are planned to assess the variation in the accuracy of these radiometers over a period of several years.

Conclusions

Within the $\pm 20\%$ bioequivalence standard used in this study, it was concluded that:

1. Overall, as a group, the dental radiometers were not bioequivalent to the gold standard laboratory-grade

Table 8 Bioequivalence results of dental radiometers tested using the PAC light

Meter	Estimate Type	RMS Proportion	Mean	Lower CI limit	Upper CI limit	Std. Error
Bluephase #1	Within $\pm 60\%$	31.2%	-351.1	-633.9	-68.4	65.7
Bluephase #2	Not within 60%	34.1%	160.5	-1,373	1693.7	356.3
Bluephase #3	<i>Within $\pm 20\%$</i>	<i>4.3%</i>	<i>-34.5</i>	<i>-182.7</i>	<i>113.8</i>	<i>34.5</i>
CureRite #1	Within $\pm 40\%$	30.8%	352.9	302.8	402.9	11.6
CureRite #2	Within $\pm 40\%$	23.6%	268.9	157.7	380.0	25.8
CureRite #3	Within $\pm 40\%$	31.5%	360.9	280.8	440.9	18.6
LEDRadiometer #1	Not within 60%	76.1%	868.9	563.4	1174.3	71.0
LEDRadiometer #2	Not within 60%	46.5%	483.9	-476.9	1444.6	223.3
LEDRadiometer #3	Not within 60%	63.5%	727.2	616.2	838.2	25.8
SDI #1	Not within 60%	91.3%	1045.5	997.0	1094.1	11.3
SDI #2	Not within 60%	90.5%	1036.9	946.0	1127.7	21.1
SDI #3	Not within 60%	89.7%	1027.5	920.1	1135.0	25.0

Units within $\pm 20\%$ are presented in italics

meters. However, individually, all three examples of the Bluephase and SDI radiometers as well as two examples of the LEDRadiometer and one CureRite meter were bioequivalent to the gold standard.

2. There was a clinically significant difference in the irradiance readings recorded by the four brands of radiometer tested in the study.
3. There can be a significant and wide variation in the irradiance readings within different examples of the same brand of dental radiometer and the clinician cannot tell which radiometer is accurate.

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Conflict of interest The authors declare that they have no conflict of interest with any of the manufacturers of the products used in this study.

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