EASTMAN
INSTITUTE FOR ORAL HEALTH

Eastman Dental

UNIVERSITY of ROCHESTER MEDICAL CENTER
Medicine *of* the Highest Order

Addendum to REPORT No. GD24-1001

Tooth whitening efficacy of Beyond Osmo Plus Whitening Gel
(14.5% Hydrogen Peroxide)

Reported on May 29, 2025

Xiaoyi Zhao, DDS, PhD
Yanfang Ren, DDS, PhD, MPH
Departments of General Dentistry and Diagnostic Sciences
University of Rochester Eastman Institute for Oral Health
Rochester, New York

Correspondence to:

Signed: May 29, 2025
Yanfang Ren, DDS, PhD, MPH
Professor and Chairman
Department of Diagnostic Sciences
University of Rochester Eastman Institute for Oral Health
625 Elmwood Avenue, Rochester, New York 14620, USA
Phone: +1 585 2735588
Email: yanfang_ren@urmc.rochester.edu

This report is an addendum to Report GD24-1001, where a whitening gel with 35% hydrogen peroxide (Beyond Max Whitening Gel) was tested for whitening efficacy. In this Addendum, additional experiments were conducted with the Beyond Osmo Plus Whitening Gel which contains 14.5% hydrogen peroxide. The testing methods followed those described in JIS T 6542:2013 for testing tooth whitening materials.

Specific Aims:

To assess the whitening efficacy of the Beyond Osmo Plus Whitening Gel on bovine incisors using the Vitapan Classical Shade Guide and the Olympus CrystalEye spectrophotometer. Tooth color changes are measured by number of shade change in values using the shade guide and by the ΔE, ΔL, Δa and Δb values in the CIE L*a*b* color space using the spectrophotometer.

METHODS:

The testing methods follow the guidelines described in JIS T 6542:2013 for testing tooth whitening materials.

Testing products: Beyond Osmo Plus Whitening Gels provided by Beyond International Inc.**,** 711 Julie Rivers Dr. Sugar Land, TX 77478 USA. The products are 14.5% hydrogen peroxide gels filled in dual-barrel syringes (Lot# Q01B25K01Z – exp: Feb-19-2027) and are fresh samples at the time of production. Two types of light sources, the BEYOND Polus Advanced Ultra Whitening Accelerator (Serial Number: 10EIE0352), and the BEYOND II Ultra Whitening Accelerator (Serial Number:11ENK0906) will be tested in combinations with the Beyond Osmo Plus Whitening Gel.

The whitening gels are applied to the tooth and dental hard tissue surfaces as follows:

1. Obtain and attach a mixing tip to the dual-barrel syringe by aligning the tip at the correct sockets. Once fitted correctly, twist the mixing tip clockwise to lock it in place. Press on the plunger and the gel mixture will discharge from the tip. Place a uniform layer of the whitening gel approximately 2mm in even thickness on the tooth or dental hard tissue surfaces.

2. Turn on the BEYOND Polus Advanced Ultra Whitening Accelerator, align the light, and adjust its distance to about 35mm to the whitening gels on the tooth surfaces, irradiate the tooth surface for 10 minutes, remove the gel with a suction tip, replace the gel as described in Step 1. Repeat the steps for 3 times for a total treatment time of 30 minutes.

   For the BEYOND II Ultra Whitening Accelerator, the treatment steps are the same as above except that the tooth surfaces with whitening gels are irradiated for 12 minutes each time for 3 times for a total treatment time of 36 minutes.

Specimen preparation: Bovine incisors were collected from local slaughterhouses from the lower jaw of freshly sacrificed bovines. The bovine incisors were cleared of soft tissues, cleaned of surface staining with a toothbrush and toothpastes (ADA manual toothbrush and Colgate Regular toothpastes), sterilized overnight with ethylene oxide, and placed in 0.1% thymol solution in normal saline before use.

Tooth whitening efficacy assessment: A total of 12 bovine incisors were divided into two groups according to the two whitening auxiliary equipment (BEYOND Polus Advanced Ultra Whitening Accelerator, n=6; and BEYOND II Ultra Whitening Accelerator, n=6). Whitening treatments with the Beyond Osmo Plus Whitening Gel were performed following the manufacturer's instruction as described in the Testing Product section (Pages 2 - 3).

a) Visual evaluations using the Vitapan Classical shade guide: The shade of the bovine incisors was assessed with the Vitapan shade guide before whitening treatments to obtain the baseline value, and assessed again after the whitening treatments to obtain the final value. The shade after whitening treatment is compared to the shade before the treatment. The number of shade changes before and after treatments were calculated. A minimum of two shade change in value to the light direction is considered as having whitening efficacy according to *JIS T 6542:2013.*

b) Spectrophotometer evaluations: The color of the labial surface of bovine incisors was assessed with a dental spectrophotometer (Olympus CrystalEye, Olympus, Tokyo, Japan) in the CIE L*a*b* color space at baseline, and after the whitening treatments. The overall color change (ΔE) in the CIE Lab color space was calculated from the

L*a*b* values before and after the whitening treatment as evaluated by the spectrophotometer. A ΔE value of at least 2, combined with an increase in ΔL* and decrease in Δb*, is considered as having whitening efficacy according to *JIS T 6542:2013.*

Outcome analysis plan: The outcomes of the whitening efficacy assessments are analyzed following the requirements specified in *JIS T 6542:2013.*

Tooth whitening efficacy analysis:

1. Comparison of the Vitapan shade values before and after the whitening treatments. The Vitapan shade guide is arranged by value (lightness) and each shade is assigned a number, with the lightest shade (B1) assigned as 1 and the darkest shade assigned as 16, as shown in Figure 3. The shade change after whitening treatment was calculated as the difference between the baseline shade and the final shade after whitening. For example, if the baseline shade is A2 (with an assigned value of 5) and the final shade after whitening is B1 (with an assigned value of 1), the number of shade change is calculated as 5 – 1 = 4, representing a 4-shade improvement after the whitening treatment.

Figure 1: Vitapan Classical shade guide arranged by value (lightness)

2. Comparison of tooth color change in the CIE L*a*b* color space: The overall color change was calculated as ΔE using the following formula:
$\Delta E = [(L_2 - L_1)^2 + (a_2 - a_1)^2 + (b_2 - b_1)^2]^{1/2}$, where L_1, a_1 and b_1 are the baseline L*, a* and b* values, and L_2, a_2 and b_2 are the final L*, a* and b* values after the

whitening treatments. Changes in lightness ($\Delta L^* = L_2 - L_1$), redness ($\Delta a^* = a_2 - a_1$) and yellowness ($\Delta b^* = b_2 - b_1$) of the teeth before and after whitening treatments were also calculated to indicate the direction of the color change. For example, a positive ΔL value indicates increase in lightness ($L_2 > L_1$), and a negative Δb value indicates decrease in yellowness ($b_2 < b_1$).

RESULTS:

Tooth whitening efficacy of Beyond Osmo Plus Whitening Gel:

The tooth whitening results for the Beyond Osmo Plus Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Osmo Plus Whitening Gel/Beyond II Ultra whitening accelerator combinations are presented in Tables 1 - 4.

1. Visual analysis using the Vitapan shade guide.
   For the Beyond Osmo Plus Whitening Gel and the BEYOND Polus Advanced Ultra Whitening Accelerator combination, the mean shade values improved from 5.33 (SD 0.52) at baseline to 1.17 (SD 0.41) after whitening, signifying a mean of 4.17 (SD 0.41) shades improvement (Table 1).

   For the Beyond Osmo Plus Whitening Gel and the BEYOND II Ultra Whitening Accelerator combination, the mean shade values improved from 5.17 (SD 0.41) at baseline to 1.33(SD 0.52) after whitening, signifying a mean of 3.83 (SD 0.75) shades improvement (Table 2).

2. Comparison of tooth color change in the CIE L*a*b* color space:
   For the Beyond Osmo Plus Whitening Gel and the BEYOND Polus Advanced Ultra Whitening Accelerator combination, the overall color change (ΔE value) was 4.42 (SD 0.71). The lightness increased (positive ΔL), the redness and the yellowness decreased (negative Δa and Δb values) (Table 3).

   For the Beyond Osmo Plus Whitening Gel and the BEYOND II Ultra Whitening Accelerator combination, the overall color change (ΔE value) was 4.36 (SD 1.00).

The lightness increased (positive ΔL), the redness and the yellowness decreased (negative Δa and Δb values) (Table 4).

CONCLUSIONS:

The following conclusions could be made from the above results:

Beyond Osmo Plus Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Osmo Plus Whitening Gel/Beyond II Ultra whitening accelerator combinations are similarly efficacious in whitening teeth. Both systems achieved greater than 4 shades of improvement on the Vitapan shade scale, and achieved ΔE values of around 4.5 in the CIE L*a*b* color space, with increased lightness (L*) and decreased yellowness (b*) after the whitening treatments.

Based on the efficacy and safety criteria set forth in the *JIS T 6542:2013* standard for testing tooth whitening materials, both the Beyond Osmo Plus Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Osmo Plus Whitening Gel/Beyond II Ultra whitening accelerator are efficacious, with significant improvements in tooth shade and color

Table 1. Visual Analysis of whitening efficacy of Beyond Osmo Plus Whitening Gel/Beyond Polus Advanced Ultra using the Vitapan shade guide (n=6)

	Baseline		**After whitening**		**Shade Change**
	Shade	Value	Shade	Value	
	A2	5	B1	1	4
	C1	6	A1	2	4
	A2	5	B1	1	4
	C1	6	B1	1	5
	A2	5	B1	1	4
	A2	5	B1	1	4
Mean		**5.33**		**1.17**	**4.17**
SD		**0.52**		**0.41**	**0.41**

Table 2. Visual Analysis of whitening efficacy of Beyond Osmo Plus Whitening Gel/Beyond II Ultra using the Vitapan shade guide (n=6)

	Baseline		**After whitening**		**Shade Change**
	Shade	Value	Shade	Value	
	A2	5	A1	2	3
	A2	5	B1	1	4
	A2	5	B1	1	4
	C1	6	B1	1	5
	A2	5	B1	1	4
	A2	5	A1	2	3
Mean		**5.17**		**1.33**	**3.83**
SD		**0.41**		**0.52**	**0.75**

Table 3. CIE L*a*b* analysis of whitening efficacy of Beyond Osmo Plus Whitening Gel/Beyond Polus Advanced Ultra using the Olympus CrystalEye Spectrophotometer #1 (n=6)**

	L_1	**a_1**	**b_1**	**L_2**	**a_2**	**b_2**	**ΔL**	**Δa**	**Δb**	**Δ*E***
	74.32	0.98	12.74	77.10	0.88	9.44	2.78	-0.11	-3.31	4.32
	70.91	0.94	12.89	72.35	0.05	8.53	1.45	-0.89	-4.36	4.68
	69.95	1.77	15.37	72.90	0.92	12.94	2.95	-0.85	-2.43	3.92
	74.32	1.04	16.40	78.03	-0.14	12.19	3.71	-1.18	-4.22	5.73
	73.94	1.07	15.45	75.89	0.92	11.98	1.95	-0.15	-3.47	3.98
	75.10	2.04	19.02	78.43	1.53	17.07	3.34	-0.51	-1.94	3.89
Mean	73.09	1.31	15.31	75.78	0.69	12.03	2.70	-0.62	-3.29	4.42
SD	2.12	0.47	2.34	2.60	0.62	3.01	0.85	0.43	0.96	0.71

**L_1, a_1 and b_1 are the baseline L*, a* and b* values, and L_2, a_2 and b_2 are the final L*, a* and b* values after the whitening treatments. $\Delta L^* = L_2 - L_1$, $\Delta a^* = a_2 - a_1$, $\Delta b^* = b_2 - b_1$

Table 4. CIE L*a*b* Analysis of whitening efficacy of Beyond Osmo Plus Whitening Gel/Beyond II Ultra using the Olympus CrystalEye Spectrophotometer #1 (n=6)**

	L_1	a_1	b_1	L_2	a_2	b_2	ΔL	Δa	Δb	Δ*E*
	73.59	1.18	16.84	76.06	0.72	13.22	2.47	-0.46	-3.62	4.41
	73.61	0.86	14.93	75.62	0.87	11.86	2.02	0.00	-3.07	3.67
	78.64	0.87	13.31	80.90	0.67	9.47	2.26	-0.20	-3.85	4.46
	73.43	1.29	15.99	78.33	0.78	12.21	4.90	-0.51	-3.78	6.21
	72.84	0.58	14.77	75.13	-0.18	11.50	2.29	-0.76	-3.27	4.06
	69.61	0.67	15.88	71.24	0.47	12.94	1.63	-0.20	-2.94	3.37
Mean	73.62	0.91	15.29	76.21	0.56	11.87	2.60	-0.36	-3.42	4.36
SD	2.90	0.28	1.23	3.25	0.38	1.34	1.17	0.27	0.38	1.00

**L_1, a_1 and b_1 are the baseline L*, a* and b* values, and L_2, a_2 and b_2 are the final L*, a* and b* values after the whitening treatments. $\Delta L^* = L_2 - L_1$, $\Delta a^* = a_2 - a_1$, $\Delta b^* = b_2 - b_1$

Equipment list:

- Beyond Polus Advanced Ultra Whitening Accelerator, Beyond International Inc., Sugar Land, Texas, USA
- Beyond II Ultra Whitening Accelerator, Beyond International Inc., Sugar Land, Texas, USA
- Olympus CrystalEye Spectrophotometer #1, Olympus Corp., Tokyo, Japan