Report #: GD24-1001 Revision No.: C



Eastman Dental



REPORT No. GD24-1001

Tooth whitening efficacy of Beyond Max Whitening Gel and its effects on dental hard tissues (Final Report)

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Date: December 19, 2024

Topline summary:

We assessed the whitening efficacy of the Beyond Max Whitening Gel (either in combination with the Beyond Polus Advanced Whitening Accelerator or the Beyond II Ultra Whitening Accelerator) and evaluated its effects on enamel surface hardness and dentin and enamel solubility using the test standards delineated in JIS T 6542:2013.

Methods: The whitening efficacy of the Beyond Max Whitening Gel on bovine incisors were assessed using the Vitapan Classical Shade Guide and the Olympus CrystalEye spectrophotometer #1. Tooth color changes were 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. The effects of the Beyond Max Whitening Gel on the surface microhardness of bovine enamel were assessed using a microhardness tester with the Knoop indenter. The Knoop microhardness numbers were compared before and after the whitening treatments to determine the changes in enamel surface microhardness. The effects of the Beyond Max Whitening Gel on the solubility of bovine enamel and dentin in comparison to a positive (1.0% citric acid, pH 3.9) and a negative (distilled water) control were assessed using a high-resolution 3D profile scanner. Surface profile of the dentin and enamel specimens after whitening treatments were compared between the test products and the controls.

Results and conclusions:

- 1. Whitening efficacy: The Beyond Max Whitening Gel are efficacious in whitening teeth. Both systems achieved greater than 4 shades of improvement and achieved ΔE values of around 5~6 in the CIE L*a*b* color space, with increased lightness (L*) and decreased yellowness (b*) after the whitening treatments.
- 2. Enamel surface microhardness: There were slight decreases in enamel surface microhardness for both the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra treatment (%KHN 6.40%) and the Beyond Max Whitening Gel/Beyond II Ultra treatment (%KHN 3.96%). The surface hardness changes are minor and well within the safety limit defined in JIS T 6542:2013.
- 3. Enamel and dentin surface dissolution: There were no statistically significantly differences in enamel or dentin surface tissue dissolution between the negative control group (distilled water) and the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra treatment group or the Beyond Max Whitening Gel/Beyond II Ultra treatment group. Enamel surface tissue loss in the two whitening treatment groups was less than 3% of the amount of tissue loss in the positive control group (1.0% citric acid); and dentin surface tissue loss in the two whitening treatment groups was less than 1% of the amount of tissue loss in the positive control group.

Based on the efficacy and safety criteria set forth in the *JIS T 6542:2013* standard for testing tooth whitening materials, both the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Max Whitening Gel/Beyond II Ultra whitening accelerator are efficacious and safe, with significant improvements in tooth shade and color and minimal impacts on the integrities of enamel and dentin after whitening treatments following the manufacturer's instructions.

OBJECTIVES and SPECIFIC AIMS:

Beyond Max Whitening Gel contains 35% hydrogen peroxide and has been successfully used for tooth whitening in dental offices worldwide for 17 years. Though it has been shown to be safe and effective in clinical applications, the Beyond Max Whitening Gel has not been tested for whitening efficacy, dental hard tissue (enamel and dentin) solubility and enamel surface hardness as specified in JIS T 6542:2013 standard.

Objectives: To assess the whitening efficacy of the Beyond Max Whitening Gel and evaluate its effects on enamel surface hardness and dentin and enamel solubility using the test standards delineated in JIS T 6542:2013.

Specific Aims:

- 1. To assess the whitening efficacy of the Beyond Max Whitening Gel on bovine incisors using the Vitapan Classical Shade Guide and the Olympus CrystalEye spectrophotometer #1. 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.
- To assess the effects of the Beyond Max Whitening Gel on the surface
 microhardness of bovine enamel using a microhardness tester with the Knoop
 indenter. The Knoop microhardness numbers are compared before and after the
 whitening treatments to determine the changes in enamel surface microhardness.
- 3. To assess the effects of the Beyond Max Whitening Gel on the solubility of bovine enamel and dentin in comparison to a positive (1.0% citric acid, pH 3.9) and a negative (distilled water) control using a high-resolution 3D profile scanner. Surface profile of the dentin and enamel specimens after whitening treatments will be compared between the test products and the controls.

METHODS:

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

<u>Testing products:</u> Beyond Max Whitening Gels provided by Beyond International Inc., 711 Julie Rivers Dr. Sugar Land, TX 77478 USA. The products are 35% hydrogen peroxide gels filled in dual-barrel syringes (Lot# A09H24H02X – exp: Feb-26-2026) 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 Max Whitening Gels

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

- 1. Step1: 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. Step 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.

<u>Specimen preparation:</u> 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.

Bovine enamel preparation for microhardness and solubility testing: Bovine incisor crowns were embedded in epoxy resins in a silicone mold (25mm x 25mm x 3mm) with the labial enamel surface exposed as the testing surface. The exposed enamel surface is polished under constant running water, first with P800 silicon carbide waterproof

paper, then with finer waterproof papers up to P4000. The enamel surface is then polished to a luster using an aluminum oxide paste with an average particle size of 0.2 μm (Enamelize™, Cosmedent, Chicago, IL, USA). The thickness of the enamel specimens so prepared are greater than 1.0mm. Surface roughness of the prepared enamel specimens were assessed with an optical-laser 3D profiler (Keyence VK X-3050, Keyence Corp., Osaka, Japan) with a resolution of 0.01nm to assure that the mean surface roughness of the specimens is below 0.2μm. The specimens are always kept moist during preparation and stored in artificial saliva at 37°C for at least 24 hours before testing.

Bovine dentin preparation for solubility testing: Bovine root dentin blocks were embedded in epoxy resins in the silicone mold with the labial root surface along the long axis exposed as the testing surface. The exposed root surface is polished under constant running water, first with P800 silicon carbide waterproof paper, then with finer waterproof papers up to P4000. The polished surface is then polished to a luster using an aluminum oxide slurry or paste with an average particle size of $0.2~\mu m$. The thickness of the dentin specimens so prepared are greater than 1.0mm. Surface roughness of the prepared root dentin specimens were assessed with the Keyence 3D profiler as described above to assure that the mean surface roughness of the dentin specimens is below $0.2\mu m$. The dentin specimens are always kept moist during preparation and stored in artificial saliva at $37^{\circ}C$ for at least 24 hours before testing.

All the prepared specimens, including the bovine incisors and the bovine enamel and dentin blocks, are stored in artificial saliva at 37°C before and after each testing procedure. The experiments are performed in air-conditioned rooms with an ambient temperature of 22°C in the laboratory at the University of Rochester Eastman Institute for Oral Health (Room 712 in the EDC building).

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 Max Whitening Gel were performed following the manufacturer's instruction as described in the Testing Product section (Page 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.

Enamel surface microhardness assessment: A total of 20 bovine enamel specimens were embedded in epoxy resin and polished from P 800 to P4000 and finished with aluminum oxide polishing pastes as described above. The specimens were divided into two groups according to two whitening auxiliary equipment (BEYOND Polus Advanced Ultra Whitening Accelerator, n=10; and BEYOND II Ultra Whitening Accelerator, n=10). Whitening treatments of the enamel surfaces are performed following the manufacturer's instruction as described in the Testing Product section (Page 3).

Before whitening treatments, enamel surface microhardness was determined with a Knoop indenter at 0.49N force with 15 seconds of dwell time using a microhardness tester (QV-1000 Microhardness Tester, Qualitest USA, Plantation, FL) to obtain the Knoop microhardness number (KHN) at baseline. Three indentations are made in 3 different locations on the enamel surface to calculate the baseline mean KHN for each specimen. After the whitening treatments, the enamel surface microhardness is measured again in the same 3 areas to calculate the final mean KHN for each

specimen. The percentage change in KHN (%KHN) is then calculated from the baseline and the final KHN numbers.

Enamel and dentin surface solubility assessment: A total of 24 bovine enamel specimens and 24 bovine dentin specimens were embedded in epoxy resin and polished from P800 to P4000 and finished with aluminum oxide polishing pastes as described above.

The 24 enamel and 24 dentin specimens were respectively divided into 4 groups of 6 each for enamel and dentin solubility assessments:

Group 1: Treatment with the Beyond Max Whitening gel and the BEYOND Polus Advanced Ultra Whitening Accelerator, n=6.

Group 2: Treatment with the Beyond Max Whitening gel and the BEYOND II Ultra Whitening Accelerator, n=6.

Group 3: Positive control with 1% citric acid at pH 3.9, n=6

Group 4: Negative control with distilled water, n=6

To allow accurate assessment of tissue dissolution depth, two pieces of polyvinyl chloride adhesive tapes in parallel are applied to the enamel or dentin surfaces to create exposed surfaces of approximately 2.0mm in width. The enamel or dentin surface areas covered by the adhesive tapes are not exposed to the whitening gels nor the positive and negative challenging solutions and will serve as the reference surface for dissolution depth measurements using the high-resolution Keyence VK X-3050 3D profilometer.

Tooth whitening treatments: Whitening treatments of the enamel and dentin surfaces for the two treatment groups are performed following the manufacturer's instruction as described in the Testing Product section (Page 3).

Positive control treatment: The test enamel and dentin specimens with partial coverage by the adhesive tapes are immersed in a beaker containing 300ml of 1.0% citric acid (pH 3.9) in a 35°C water bath. The solution is stirred at 270 revolutions per minute for 60 minutes using an overhead stirrer (Heidolph RZR2020 Overhead Stirrer, Heidolph

Instruments Co., Schwabach, Germany). This positive treatment control protocol complies to the *JIS T 6542:2013* standard.

Negative control treatment: The test enamel and dentin specimens with partial coverage by the adhesive tapes are immersed in a beaker containing 300ml of distilled water in a 35°C water bath. The water is stirred at 270 revolutions per minute for 60 minutes using the Heidolph overhead stirrer as described above. This negative treatment control protocol complies to the JIS T 6542:2013 standards.

Enamel and dentin tissue dissolution depth measurements: After the whitening and the positive and negative control treatments, the adhesive tapes are removed to expose the reference surfaces on the enamel and dentin specimens. Three different locations on each specimen are scanned perpendicular to the long axis of the treated area, spanning

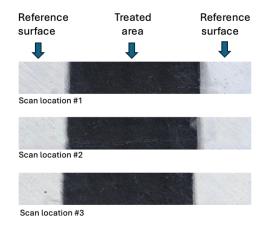


Figure 1: Three locations on enamel surfaces are scanned with the Keyence VK X-3000 3D scanner.

across the entire width of the exposed area and the intact reference surfaces on each side using the Keyence VK X-3050 3D profile scanner with both the laser and coaxial light sources (Figure 1).

The surface profiles of the 3 scanned locations from each specimen are analyzed using the VK-X 3050 Multifile Analyzer software. Using the untreated surfaces on each side of the treated area as the reference plane, the mean depth of the treated area relative to the reference plane were measured for each specimen. The mean values of the mean depth of the 3 scanned locations are calculated to represent the tissue dissolution depth of each specimen (Figure 2).

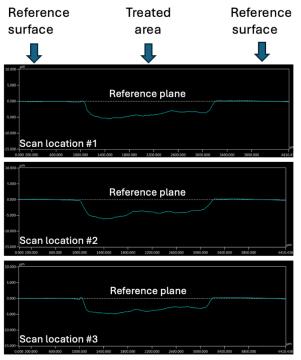


Figure 2: Three locations on enamel surfaces are measured for mean depth of tissue loss relative to the reference plane using the Keyence VK X-3000 Multifile Analyzer.

<u>Outcome analysis plan:</u> The outcomes of the whitening efficacy, enamel surface microhardness, and enamel and dentin solubility 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 3: 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 L₁, a₁ and b₁ are the baseline L*, a* and b* values, and L₂, a₂ and b₂ 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 (L₂ > L₁), and a negative Δb value indicates decrease in yellowness (b₂ < b₁).

Enamel surface microhardness analysis: Baseline and final KHN were calculated as the mean KHN numbers from the 3 locations on each specimen in each treatment group. The percentage change in KHN (%KHN) is calculated from the mean baseline and the mean final KHN numbers for each specimen in each treatment group.

Enamel and dentin dissolution depth analysis: We will compare the mean depths of tissue loss (enamel and dentin) among the 4 experimental groups as described in the Method section using one-way Analysis of Variance (ANOVA) and the post hoc Fisher's Least Significant Difference (LSD) test at an alpha level of 0.05. We expect that there are statistically significant differences among the 4 groups, and the post hoc pair-wise comparisons will help us to identify if any differences exist between the two treatment groups and between each treatment group and the positive or negative controls.

RESULTS:

Tooth whitening efficacy of Beyond MAX Whitening Gel:

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

Visual analysis using the Vitapan shade guide.
 For the Beyond Max 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 Max Whitening Gel and the BEYOND II Ultra Whitening Accelerator combination, the mean shade values improved from 5.17 (SD 0.41) at baseline to 1.00 (SD 0.00) after whitening, signifying a mean of 4.17 (SD 0.41) shades improvement (Table 2).

2. Comparison of tooth color change in the CIE L*a*b* color space: For the Beyond Max Whitening Gel and the BEYOND Polus Advanced Ultra Whitening Accelerator combination, the overall color change (ΔE value) was 4.92 (SD 1.30). The lightness increased (positive ΔL), the redness and the yellowness decreased (negative Δa and Δb values) (Table 3).

For the Beyond Max Whitening Gel and the BEYOND II Ultra Whitening Accelerator combination, the overall color change (ΔE value) was 6.35 (SD 1.81). The lightness increased (positive ΔL), the redness and the yellowness decreased (negative Δa and Δb values) (Table 4).

Enamel surface microhardness analysis:

The effects of the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Max Whitening Gel/Beyond II Ultra whitening accelerator combinations on

enamel surface microhardness are presented in Tables 5 - 6. There was a mean of 6.40% (SD 2.49) decrease in enamel surface microhardness after whitening treatments with the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra combination, and a mean of 3.96% (SD 1.84) decrease in enamel surface microhardness after whitening treatments with the Beyond Max Whitening Gel/Beyond II Ultra combination.

Enamel and dentin tissue loss analysis:

Enamel and dentin surface tissue losses, measured as the mean surface dissolution depth after treatments with Beyond Max Whitening Gel/Beyond Polus Advanced Ultra, Beyond Max Whitening Gel/Beyond II Ultra whitening treatments, a positive control (1.0% citric acid) and a negative control (distilled water), are presented in Tables 7 – 8.

These results indicate that enamel and dentin tissue losses were minimal after whitening treatments with both the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Max Whitening Gel/Beyond II Ultra whitening accelerator combinations. Enamel surface loss for the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra combination was $0.146\pm0.139~\mu m$, which is 2.1% of the amount of tissue loss $(6.976\pm1.036\mu m)$ in the positive control group. Enamel surface loss for the Beyond Max Whitening Gel/Beyond II Ultra combination was $0.173\pm0.110~\mu m$, which is 2.5% of the amount of tissue loss in the positive control group (Table 7). Dentin surface loss for the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra combination was $0.076\pm0.058~\mu m$, which is 0.6% of the amount of tissue loss ($13.000~\pm1.834\mu m$) in the positive control group. Dentin surface loss for the Beyond Max Whitening Gel/Beyond II Ultra combination was $0.074\pm0.091~\mu m$, which is 0.6% of the amount of tissue loss in the positive control group (Table 8).

Analysis of Variance (ANOVA) showed that there were significant differences in enamel and dentin surface tissue losses among the 4 comparison groups. The post hoc Fisher's Least Significant Difference (LSD) test showed that positive control caused significantly more enamel and dentin tissue losses than the two whitening treatment groups and the negative control. There were no statistically significant differences in enamel or dentin

tissue losses between the whitening treatment groups and the negative controls (Table 9-10).

CONCLUSIONS:

The following conclusions could be made from the above results:

- 4. Whitening efficacy: The Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Max 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 5~6 in the CIE L*a*b* color space, with increased lightness (L*) and decreased yellowness (b*) after the whitening treatments.
- Enamel surface microhardness: There were slight decreases in enamel surface microhardness for both the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra treatment (%KHN 6.40%) and the Beyond Max Whitening Gel/Beyond II Ultra treatment (%KHN 3.96%).
- 6. Enamel and dentin surface dissolution: There were no statistically significantly differences in enamel or dentin surface tissue dissolution between the negative control group (distilled water) and the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra treatment group or the Beyond Max Whitening Gel/Beyond II Ultra treatment group. Enamel surface tissue loss in the two whitening treatment groups was less than 3% of the amount of tissue loss in the positive control group (1.0% citric acid); and dentin surface tissue loss in the two whitening treatment groups was less than 1% of the amount of tissue loss in the positive control group.

Based on the efficacy and safety criteria set forth in the *JIS T 6542:2013* standard for testing tooth whitening materials, both the Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and the Beyond Max Whitening Gel/Beyond II Ultra whitening accelerator are efficacious and safe, with significant improvements in tooth shade and color and minimal impacts on the integrities of enamel and dentin after whitening treatments following the manufacturer's instructions.

Tables

Table 1. Visual Analysis of whitening efficacy of Beyond Max Whitening Gel/Beyond Polus Advanced

Ultra using the Vitapan shade guide (n=6)

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

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

	Baseline		After wi	nitening	Shade Change
	Shade	Value	Shade	Value	
	A2	5	B1	1	4
	A2	5	B1	1	4
	A2	5	B1	1	4
	C1	6	B1	1	5
	A2	5	B1	1	4
	A2	5	B1	1	4
Mean		5.17		1.00	4.17
SD		0.41		0.00	0.41

Table 3. CIE L*a*b* analysis of whitening efficacy of Beyond Max 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	∆a	Δ b	∆ E
	70.06	2.21	16.69	74.03	0.74	13.24	3.97	-1.47	-3.45	5.46
	73.21	0.89	11.71	75.22	0.47	8.62	2.01	-0.42	-3.09	3.71
	73.33	1.13	13.84	75.88	0.46	10.79	2.55	-0.67	-3.05	4.03
	73.62	0.51	13.07	80.62	0.03	11.18	7.00	-0.48	-1.89	7.27
	78.93	0.30	16.38	80.27	-0.53	11.94	1.35	-0.83	-4.44	4.71
	72.36	1.39	12.89	75.12	0.94	9.56	2.76	-0.45	-3.32	4.35
Mean	73.59	1.07	14.10	76.86	0.35	10.89	3.27	-0.72	-3.21	4.92
SD	2.92	0.68	2.01	2.84	0.53	1.65	2.02	0.40	0.82	1.30

^{**}L₁, a₁ and b₁ are the baseline L*, a* and b* values, and L₂, a₂ and b₂ 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 Max 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	∆a	Δb	∆ E
	71.09	2.54	16.38	76.57	0.96	11.47	5.48	-1.58	-4.91	7.53
	72.79	1.93	19.92	75.71	0.10	12.86	2.92	-1.83	-7.06	7.86
	72.15	0.75	15.46	76.44	0.16	8.70	4.29	-0.59	-6.76	8.03
	73.67	0.99	12.93	76.01	0.46	10.53	2.34	-0.53	-2.41	3.39
	75.25	0.64	16.28	80.14	0.06	12.83	4.89	-0.59	-3.45	6.01
	75.76	1.14	14.91	78.24	1.03	10.23	2.48	-0.11	-4.68	5.30
Mean	73.45	1.33	15.98	77.19	0.46	11.10	3.73	-0.87	-4.88	6.35
SD	1.81	0.75	2.30	1.69	0.44	1.62	1.33	0.67	1.82	1.81

^{**}L₁, a₁ and b₁ are the baseline L*, a* and b* values, and L₂, a₂ and b₂ 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 5. Effects of Beyond Max Whitening Gel/Beyond Polus Advanced Ultra whitening treatments on enamel surface microhardness (n=10)*

	l	KHN		
	Baseline	After whitening	Δ KHN	%KHN
	306.99	286.00	-20.98	6.84
	273.89	260.47	-13.42	4.90
	324.45	313.66	-10.79	3.32
	306.12	301.71	-4.41	1.44
	302.14	281.47	-20.67	6.84
	281.27	258.64	-22.63	8.05
	298.02	274.93	-23.08	7.75
	298.25	269.48	-28.77	9.65
	319.14	292.48	-26.66	8.35
	287.31	267.56	-19.74	6.87
Mean	299.76	280.64	-19.12	6.40
SD	15.83	18.02	7.47	2.49

^{*}KHN – Knoop's microhardness number; Δ KHN – changes in KHN after whitening; %KHN – percentage change in KHN after whitening

Table 6. Effects of Beyond Max Whitening Gel/Beyond II Ultra whitening treatments on enamel surface microhardness (n=10)*

		KHN		
	Baseline	After whitening	ΔKHN	%KHN
	275.39	273.78	-1.60	0.58
	307.60	294.34	-13.26	4.31
	296.40	284.88	-11.52	3.89
	314.49	304.86	-9.63	3.06
	321.67	300.72	-20.95	6.51
	298.84	279.30	-19.54	6.54
	338.38	330.91	-7.47	2.21
	289.19	279.90	-9.28	3.21
	302.26	286.94	-15.32	5.07
	298.73	286.76	-11.97	4.01
Mean	304.30	292.24	-12.06	3.96
SD	17.54	16.68	5.69	1.84

^{*}KHN – Knoop's microhardness number; Δ KHN – changes in KHN after whitening; %KHN – percentage change in KHN after whitening

Table 7. Effects of Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and Beyond Max Whitening Gel/Beyond II Ultra whitening treatments on **enamel** surface tissue loss (μ m) in comparison to a positive and a negative control (n=6 in each group)*

	Polus Advanced	Beyond II Ultra	Positive Control	Negative Control
	-0.187	-0.109	-6.990	-0.004
	-0.157	-0.232	-7.546	-0.005
	-0.031	-0.122	-6.002	-0.003
	-0.048	-0.313	-8.154	-0.006
	-0.398	-0.013	-7.677	-0.005
	-0.056	-0.247	-5.487	-0.005
Mean	-0.146	-0.173	-6.976	-0.005
SD	0.139	0.110	1.036	0.001

^{*}Positive Control – 1.0% citric acid at pH 3.9; Negative Control = distilled water

Table 8. Effects of Beyond Max Whitening Gel/Beyond Polus Advanced Ultra and Beyond Max Whitening Gel/Beyond II Ultra whitening treatments on dentin surface tissue loss (μm) in

comparison to a positive and a negative control (n=6 in each group)*

	Polus Advanced	Beyond II Ultra	Positive Control	Negative Control
	-0.090	-0.194	-11.626	-0.015
	-0.011	-0.188	-14.452	-0.030
	-0.137	-0.006	-11.964	-0.011
	-0.138	-0.011	-10.661	-0.003
	-0.068	-0.031	-15.295	-0.027
	-0.009	-0.016	-14.001	-0.003
Mean	-0.076	-0.074	-13.000	-0.015
SD	0.058	0.091	1.834	0.012

^{*}Positive Control – 1.0% citric acid at pH 3.9; Negative Control = distilled water

Table 9: Pairwise comparisons on enamel tissue losses among the 4 study groups

Pairwise comparisons	Mean Difference	Critical Difference	p values*
Polus Advanced, Beyond II Ultra	0.026	0.633	0.9313
Polus Advanced, Positive Control	6.830	0.633	<0.0001
Polus Advanced, Negative Control	-0.141	0.633	0.6461
Beyond II Ultra, Positive Control	6.803	0.633	<0.0001
Beyond II Ultra, Negative Control	-0.168	0.633	0.5860
Positive Control, Negative Control	-6.971	0.633	<0.0001

^{*}ANOVA post hoc FLSD tests, p < 0.05 indicates statistical significance

Table 10: Pairwise comparisons on dentin tissue losses among the 4 study groups

Pairwise comparisons	Mean Difference	Critical Difference	p values*
Polus Advanced, Beyond II Ultra	-0.001	1.106	0.9983
Polus Advanced, Positive Control	12.924	1.106	<0.0001
Polus Advanced, Negative Control	-0.061	1.106	0.9100
Beyond II Ultra, Positive Control	12.926	1.106	<0.0001
Beyond II Ultra, Negative Control	-0.060	1.106	0.9118
Positive Control, Negative Control	-12.985	1.106	<0.0001

^{*}ANOVA post hoc FLSD tests, p < 0.05 indicates statistical significance

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
- QV-1000 Microhardness Tester, Qualitest USA, Plantation, Florida, USA
- Keyence VK X-3050 3D profile scanner, Keyence Corp., Osaka, Japan