YAMAKIN

From Production Skills to Scientific Knowledge,
and Onward to Fusion with Medical Science

A·UNO
Product Report

Basic Knowledge of Universal Shade Type Composite Resin and YAMAKIN's unique color-matching technology, "Camouflage Effect".

Edited by YAMAKIN Ph.D. Group

Index

1 Introduction

Outline of universal shade composite resin and development history of "A•UNO"

Direct composite resin has been used in a variety of cases and also satisfies patients' requests for white teeth since the idea of MI (Minimal Intervention) treatment has recently gained popularity. Direct composite resin is used not only for the treatment of small caries on the tooth surface layer but also for the restoration of molars. Therefore, it requires high strength to withstand occlusion. In addition, direct composite resin exhibits a number of all-around exceptional qualities such as durability, workability, color tone, and fluoride release property. In particular, good rheology (formability and fluidity) is needed to avoid posing a workability challenge for doctors. And fluoride release property is proposed for the prevention of secondary caries and it is believed that the sustained release and recharge property can be effective.

Furthermore, in recent years, the ability to easily reproduce the color of natural teeth has become desirable. Therefore, universal shade type direct composite resins are attracting a great deal of attention, as they save the trouble of shade selections and make it easy to control inventory.

Universal shade type direct composite resin is a product with a different color tone design from conventional direct composite resins[1)]. As Figures 1-1 and 1-2 show, conventional direct composite resins come in a range of different shades, such as A1, A2, A3, etc., in order to match the color of each tooth substances. The universal shade type, on the other hand, is designed to be used with only one shade and not require shade taking or shade selection for any of the basic shades (16 colors).

In addition to the chameleon effect demonstrated by adjusting light transmission and light diffusivity, which is also applied to our conventional product "TMR-Z Fill 10.", in order to develop a universal shade type direct composite resin, YAMAKIN CO., LTD. (hereinafter referred to as YAMAKIN) has optimized the balance of transparency, shielding property, and saturation using our unique color-matching technology, and focused on color tone design so that many cases can be covered simply with a single color. YAMAKIN has leveraged its filler technology, which has evolved through the development of resin products to date, and its unique color-matching technology to create a new composite resin product, "A·UNO", which maintains both fluoride release and strength while being suitable for a wide variety of cases.

Based on the concept of easily reproducing a wide range of natural tooth color tones in a shade-free manner, this product has been developed in consideration of the required strength and workability. In this technical report, "A·UNO" is introduced from various viewpoints. We hope that this product will be of interest to you and that you will make use of it as an aid in your future dental treatment.

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What is the YAMAKIN Ph.D. Group?
This is a group of experts in various specialized fields who bring together their knowledge, experience and technical expertise to act as a prime motivator in the continuous generation of innovation.

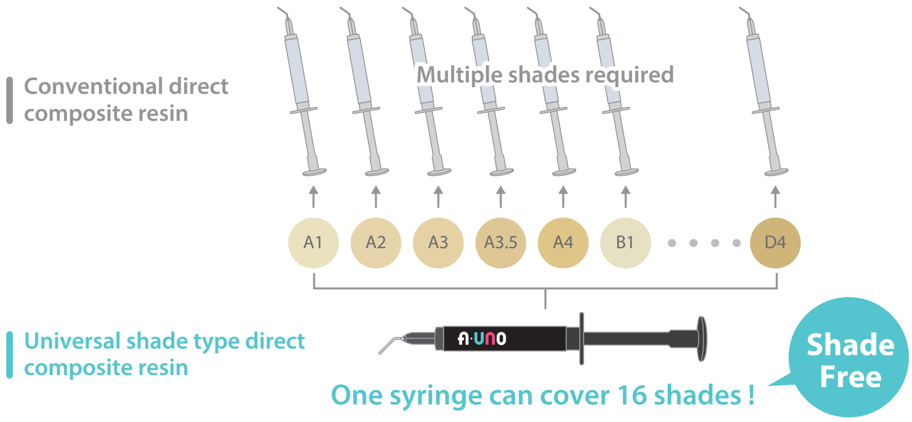


Figure 1-1 Summary of Universal Shade-type Direct Composite Resin (Shade Free)

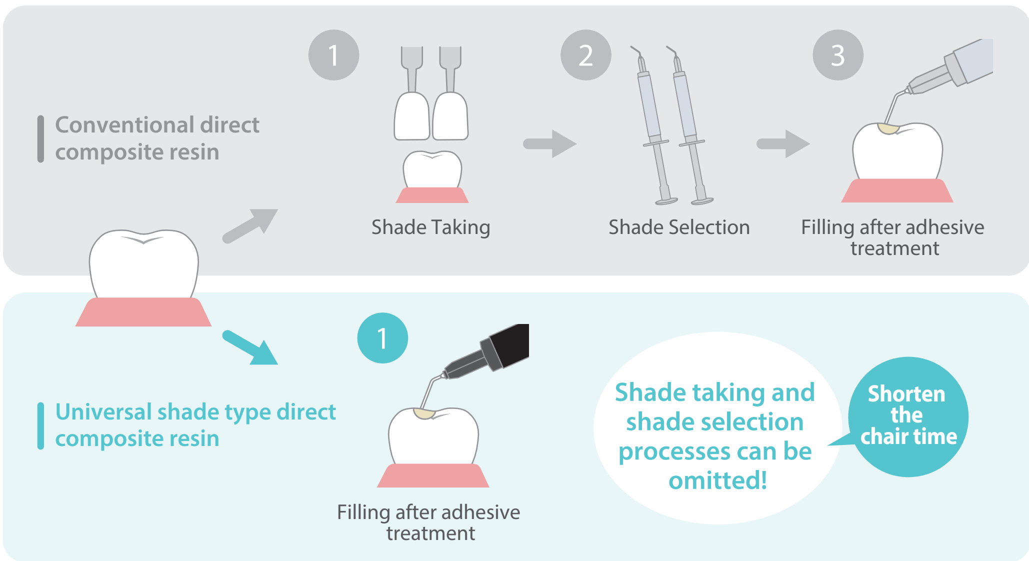


Figure 1-2 Summary of Universal Shade Type Composite Resin (Shorten Chair Time)

About the definitions of the terms "Universal type" and "Universal shade type"

The word "Universal" has a wide range of meaning, such as "general purpose" or "for everyone". In the dental field, "Universal" is often used to refer to bonding materials and cements that are applicable to various materials without the need to change the bonding or cement depending on the materials. Also, since there were two types of direct composite resins, one for anterior teeth and the other for molars, depending on strength and esthetics, the term "Universal type" in composite resins was used to refer to a general-purpose type of resin that is superior in both strength and esthetics and can be used for both anterior teeth and molars. With the development of the "Flow type" which has good flowability and filling workability for cavities, the "Universal type" now generally refers to a type with a high filler content and a clay-like paste before curing.

As mentioned above, the versatility of direct composite resins has further evolved in recent years, with the development of products collectively known as "Universal shade type direct composite resins" meaning that they "cover a wide range of shades of tooth substances with one shade". Thus, "Universal" is used with multiple meanings in direct composite resins. Therefore, the definitions of "Universal type" and "Universal shade type" in this report are defined as follows.

"Universal type"

Direct composite resin with a high filler content and excellent formability in the form of a paste (distinguished from the flow type).

"Universal shade type"

A single shade of composite resin that can be used for a wide range of shades of tooth substances.

2 Basic knowledge of composite resins for dental fillings

2.1 What is composite resin?

Direct composite resins are organic-inorganic composites and consist of monomers such as matrices as their organic component and fillers such as silica glass as their inorganic component. Monomers are organic materials that have the property of changing into polymers through polymerization curing. In composite resins, crosslinkable methallylate monomer mixtures are often used because of their superior strength and biological safety. The nature of polymerization, which transforms flowable monomers into solid polymers, is an important property that is related to the workability, color tones, and durability of composite resin restorations.

In other words, while the monomer can be freely shaped before polymerization, it serves to provide high strength that allows it to be used on occlusal surfaces after polymerization.

Figure 2-1-1 shows Urethane Dimethacrylate (UDMA), Bisphenol A Diglycidyl Methacrylate (Bis-GMA), and Triethylene Glycol Dimethacrylate (TEGDMA), which are widely used as resin-based restorations for dental applications. Various other monomers are also used, and properties such as viscosity, transparency, and polymerization shrinkage of resin pastes can be adjusted by mixing several monomers with different properties.

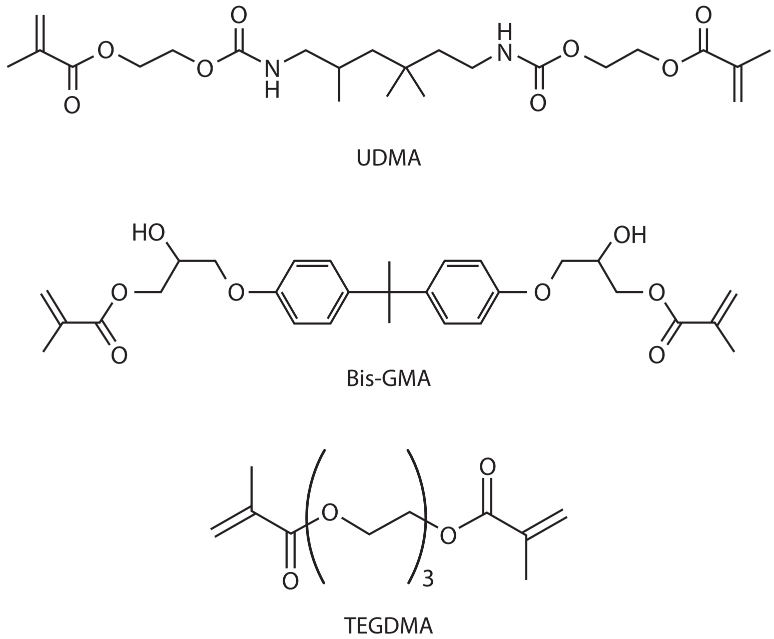


Figure 2-1-1 Examples of Monomers Used in Dental Resin-based Restorations

The inorganic filler is made of silica, alumina, or zirconia in particulate form, which is filled into the monomer to form an uncured composite resin. Filler filling can impart mechanical strength, such as flexural strength and hardness, to the properties of the matrix. Various types of fillers are used, including inorganic fillers with sizes ranging from submicron to several microns, nano-sized colloidal silica, and organic and inorganic composite fillers made by filling monomers with nano-fillers in advance, polymerizing and curing, and then pulverizing the resulting substance. By changing the components and shapes used in inorganic fillers, the range of functions can be expanded, such as improving polishability and workability, and imparting fluoride sustained release properties. In addition, the operation of the paste is adjusted by using a combination of these fillers (Figure 2-1-2).

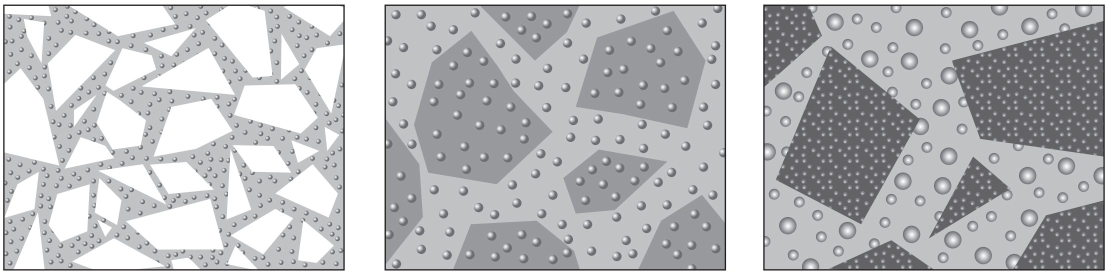


Figure 2-1-2 Schematic Diagram of Filler Filling

As shown above, though each monomer and inorganic filler plays an important role, sufficient strength and durability cannot be obtained unless they are firmly bonded at the interface. This is because fractures and breaks in composite materials occur at the interface between the matrix and the filler. Basically, the monomers are lipophilic, and the surfaces of inorganic fillers are hydrophilic. Therefore they do not have a high affinity for each other. The method used to solve this problem is surface treatment with a silane coupling agent. The surface of inorganic filler treated with a silane coupling agent is modified to become lipophilic and have a high affinity for monomers. In addition, silane coupling agents have radical-polymerizable groups in their molecules. Therefore they have the ability to react simultaneously during the polymerization of monomers. As a result, high filler content of inorganic fillers is possible, and after polymerization curing, they are firmly bonded and integrated with the polymer matrix, contributing greatly to the high strength and high durability of composite resins. As described above, monomers, inorganic fillers, and their interfaces must fulfill their respective roles sufficiently for composite resins to meet the required performance as dental materials.

2.2 Reaction Mechanism of Photo-radical Polymerization Reaction by Photosensitizers

To obtain a polymer from a monomer, a specific reaction called a polymerization reaction is required. Polymerization reactions are classified into chain reactions and sequential reactions. In chain reactions, when a polymerization active species is generated from a monomer, it immediately reacts with another monomer, followed by a rapid reaction to another monomer (Figure 2-2-1). As a result, the monomer is instantaneously transformed into a mixture of a high molecular weight polymer and an unpolymerized monomer by a chain reaction. On the other hand, sequential reactions require a certain amount of time for the polymer to reach a high molecular weight because of the slow consumption of monomers. In the case of monomers with multiple polymerizable groups in the molecule (crosslinkable monomers), the polymer forms a network structure (crosslinked structure) through polymerization, and as polymerization progresses and the density of the polymer network structure increases, the resulting substance exhibits high solvent resistance (i.e., it does not dissolve even in solvents), and stable strength in the oral cavity for a long time.

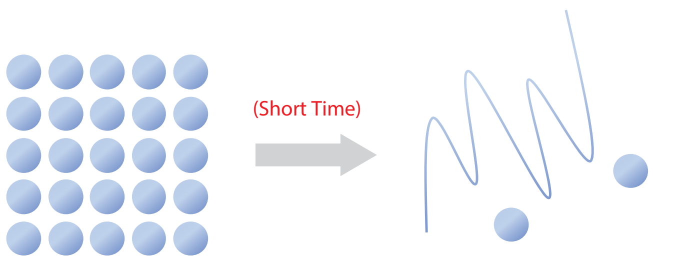


Figure 2-2-1 Chain Reaction (Radical Polymerization)

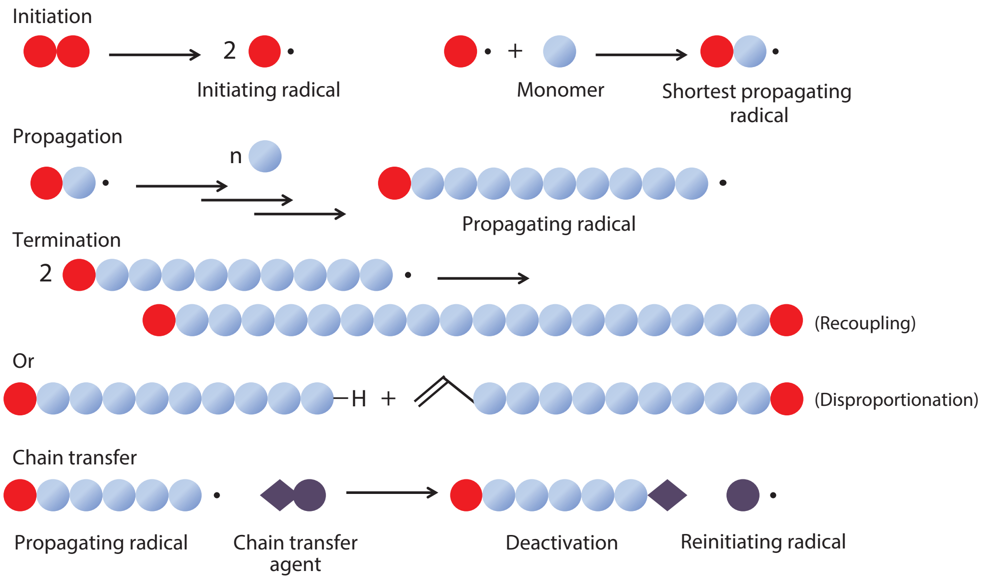


Figure 2-2-2 Four Elementary Reactions in Radical Polymerization (Initiation, Propagation, Termination, and Chain Transfer)

When the composite resin is irradiated with light, radical polymerization of the monomer occurs and a polymer is formed and cured. This radical polymerization usually does not proceed with the monomer alone, but uses an initiator, that is a thermal sensitizer for polymerization by heating or a photosensitizer for polymerization by light irradiation. Most composite resins are polymerized and cured by light irradiation using photosensitizers such as Camphorquinone (CQ) and accelerators such as tertiary amines. Radical polymerization consists of four types of elementary reactions: Initiation, Propagation, Termination, and Chain Transfer, as shown in Figure 2-2-2. In the case of photoirradiation polymerization, the photosensitizer generates an initiating radical upon light irradiation, and the addition of the initiating radical to the monomer generates a propagating radical. These two types of reactions form the Initiation. During Propagation, propagating radicals repeatedly add themselves to the monomer one after the other, growing to a high molecular weight. At Termination, recombination or bimolecular disproportionation of propagating radicals renders the propagating radicals inactive, and a single or bimolecular polymer chain is formed.

2.3 Initiating Reaction and Light Irradiator

Radical polymerization of composite resins is initiated by light irradiation from a light irradiator, but the light used for initiation must be light that is absorbed by the photosensitizer. CQ is widely used as a photoinitiator for photoinitiating polymerization of dental materials, and is excited by light irradiation in this wavelength region because it shows an absorption maximum at around 470 nm. Photoexcited CQ draws hydrogen from hydrogen donors such as tertiary amines to form initiating radicals. Visible light irradiation of CQ/amine initiators produces two types of radicals, but CQH· does not add to monomers due to its large steric hindrance. On the other hand, R "CH(·)N(R)(R2') causes addition to the monomer and becomes the initiating radical (Figure 2-3-1).

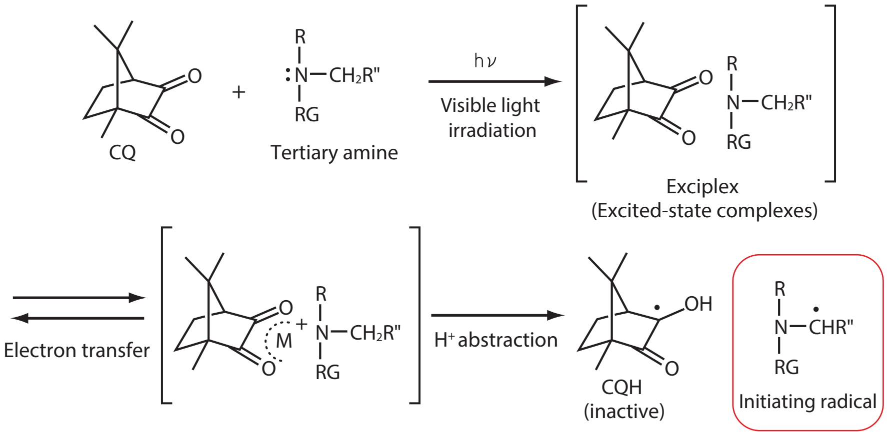


Figure 2-3-1 Radical Formation from Camphorquinone/ Tertiary Amine Initiator System by Visible Light Irradiation

In other words, resin materials that use CQ as a photosensitizer polymerize and cure when irradiated with light at a wavelength of around 470 nm. The polymerization rate and the physical properties of the polymer produced (dental material after curing) differ depending on the intensity of the irradiated light. Light-curing material must be irradiated with light of the appropriate wavelength and intensity . If not appropriate, the initiation reaction may not proceed sufficiently, resulting in insufficient polymerization, and the material after polymerization may not exhibit its original properties. Currently, light irradiators with various light sources and light intensity are commercially available. Light sources include Halogen lamps, plasma lamps, and LED lamps, but in recent years, LED light irradiators have become the mainstream. In addition, LED light irradiators with maximum irradiance (Table 2-3-1) are now available to shorten the curing time of resin materials, and the irradiation time that can be set is also becoming shorter. In addition, products equipped with not only blue LED (about 470 nm) but also purple LED (about 40 nm) are now available for use in glazing material and whitening. Each product has a wide variety of characteristics, and light exposure must be applied for the appropriate amount of light and time for the composite resin used. In many cases, IFU indicate that LED lamps can reduce irradiation time by half when compared to halogen lamps and LED lamps. This is because LED lamps can irradiate light of 470 nm, the excitation wavelength of CQ, to a more limited extent than halogen lamps, and can achieve a sufficient polymerization rate even with a short irradiation time. The development of such light sources has also contributed to the efficiency of dental treatment.

Table 2-3-1 Examples of Commercial Light Illuminator (LED)

Seller	Product Name	Effective wavelength range (nm)	Maximum irradiance (mW/cm^2)
YAMAKIN CO., LTD./ PIERCE CORP.	Penguin α	380 ~ 415 440 ~ 480	2400
PIERCE CORP.	Delight ortho	420 ~ 490	2700
Ultradent Products, INC.	VALO LED Curing Light	395 ~ 480	3200
	VALO Cordless	395 ~ 480	3200
	VALO GRAND LED Curing Light	395 ~ 480	3200
	VALO GRAND Cordless	395 ~ 480	3200
SHOFU INC.	VALO Ortho	395 ~ 480	3200
	VALO Ortho Cordless	395 ~ 480	3200
J. MORITA MFG. CORP.	PenCure 2000	405 ~ 460	2000
GC CORP.	SlimLight	390 ~ 480	2000
Hakusui Trading CO., LTD.	miniLED Ⅲ	420 ~ 480	2200
Ivoclar Vivadent, INC.	Bluephase N G4	385 ~ 515	2000
	Bluephase 20i	385 ~ 515	2000
	Bluephase Style 20i	385 ~ 515	2000
	Bluephase PowerCure	385 ~ 515	3000
Micro Tech. CORP.	LEDEX turbo WL-090	440 ~ 480	2400
	LEDEX WL-090	440 ~ 480	3200
Forest-one CO.,LTD.	FUSION5	420 ~ 490	4000
Dentaltechnika KFT.	NOBLESS	430 ~ 490	3000
	NOBLESS A	385 ~ 515	3000
Apixia CORP.	LITEX 696 Turbo	440 ~ 490	2500
Dentrade KFT.	D-LUX LED	420 ~ 490	2400
	D-LUX Pen	385 ~ 430 440 ~ 515	2300
B.S.A. Sakurai CO., LTD	X Light	430 ~ 480	2500
	X Light PLUS	385 ~ 515	3200
WSPT japan LLC.	HABILETE	385 ~ 515	2300

2.4 Technological Development of Composite Resin

At the time of development, composite resins were only clay-like pastes that were built up with a spatula, but many composite resins on the market today are available in a flow type, which can be injected directly into cavities using a syringe, and to facilitate filling of deep cavities, various viscosities have been developed for each product, ranging from those with very high flowability (high flow) to those with low flowability (low flow) that can also be shaped with septa and other tools. There have been remarkable technological developments in composite resins, such as flow-type composite resins with high strength that can be used on molar occlusal surfaces, and bulk-type composite resins that exhibit a curing depth of 4.0 mm with a single light irradiation. In recent years, Universal shade type composite resins, which do not require shade selection, have attracted particular attention. This type not only easily reproduces the color tone of natural teeth, but also reduces inventory loss, which may contribute to the Sustainable Development Goals (SDGs). The color matching technology of the Universal shade type composite resin "A·UNO" will be covered in the following chapter.

3 Concept of A·UNO

3.1 Overview of "Camouflage Effect", a unique color matching technology

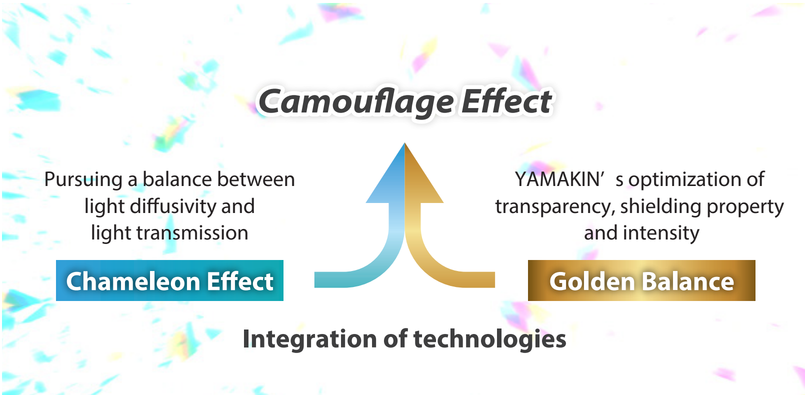


Figure 3-1-1 Unique Color Matching Technology "Camouflage Effect"

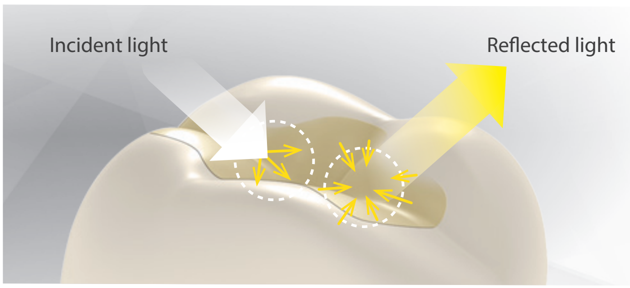


Figure 3-1-2 Pursuing A Balance Between Light Diffusivity and Light Transmission (Chameleon Effect)

As shown in Figure 3-1-1, the "Camouflage effect" used in "A·UNO" combines two major color matching techniques. The first is "Pursuing a balance between light diffusivity and light transmission". Light incident on "A·UNO" is scattered by its light diffusivity and reaches the surrounding tooth substances. Through the process of scattering, the filling area becomes blurred and appears to blend in with the color of the surrounding tooth substances (Figure 3-1-2). In addition, the light reflected from "A·UNO" is diffused into the surrounding tooth substances as mentioned above. Therefore, the color of "A·UNO" is blended with the surrounding tooth substances. This ability to transmit light while diffusing it is the fundamental technology of A·UNO's color compatibility. This property, also known as the chameleon effect, is also applied to our conventional product, "TMR-Z Fill 10."

As shown in Figures 3-1-3 and 3-1-4, "A·UNO" can blend well with cavity models of different shades.

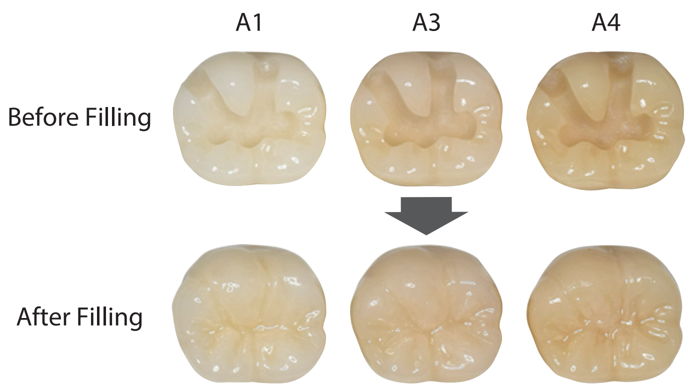


Figure 3-1-3 Apply A • UNO on A1, A3 and A4 shade cavity models

Figure 3-1-4 Artificial tooth filled with "A • UNO" in 16 shades

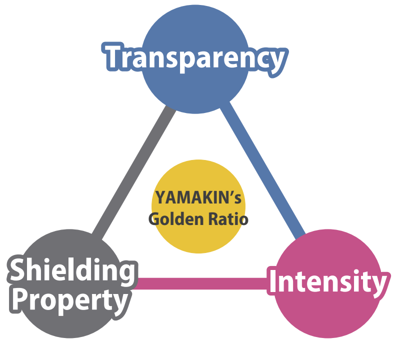


Figure 3-1-5 YAMAKIN's Golden Ratio of Transparency, Shielding Property and Intensity

Another technology is the "YAMAKIN's Golden Ratio of Transparency, Shielding Property and Intensity" shown in Figure 3-1-5. Through repeated trial and error regarding transparency, shielding property, and intensity, we were able to find a design that reduced the influence of the base color tone and made it possible to reduce the difference in brightness between the resin filling part and the tooth substances.
The details of this technique are described in 3.5. This unique technology allows "A·UNO" to not only match a wide range of tooth color tones, but also to perform well in a wide range of cavity conditions which are assumed clinical practice.
These two technologies were combined to create "A·UNO", featuring the "Camouflage Effect", a unique color matching technology developed by YAMAKIN. Next, basic information about color is presented, followed by a detailed explanation of the color matching properties of A·UNO.

3.2 What is color?

The three colors of blue, red, and green in the YAMAKIN's logo represent respectively the "sea and sky," "sun" and "trees" of Kochi Prefecture, the development and manufacturing base. This design represents the company's commitment to delivering products with excellent quality based on innovative ideas in a rich natural environment. It is also used as a company badge (Figure 3-2-1).

Figure 3-2-1 YAMAKIN's Logo

Interestingly, while blue, red, and green are the three primary colors of light, there are significant differences in the mechanisms by which humans feel the "blue of the sky," the "green of trees," and the “red of the sun”. The blue of the sky is caused by the scattering of light in the atmosphere at wavelengths that are perceived as blue by the human eye , and the colors of grass and leaves are caused by the reflection of light at wavelengths that appears green to the human eye. The red color of the sun follows the image and culture of Japanese people (the color of sunsets and the Japanese flag), and is originally white, almost yellow, while in Europe and the United States, it is painted yellow, and there are regional differences[2].

In his book "OPTIKS" published in 1704, physicist Isaac Newton stated the famous phrase “The rays are not colored” [3]. In other words, light itself has no color, but the sensation of "color" is generated only when light enters the eye and is transmitted to the cerebrum, and light itself is only a trigger for generating such sensation. In the following sections, the physiology of the human visual system and color vision will be briefly discussed, and the "Camouflage Effect," a color matching technology for "A·UNO" will be explained in detail.

3.3 Structure of Eye and Light

The structure of the human eye is similar to that of a camera. It includes an "iris", which is a control that adjusts the amount of light, a "crystalline lens", which acts as a lens to adjust focus, a "retina", which accepts light and projects an image, and neurocytes that transmit visual information to the brain. The most important part in the eye that receives light is the retina (Figure 3-3-1) [2, 4-8].

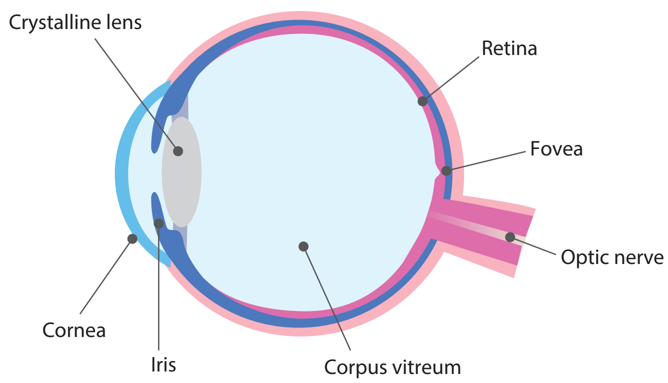


Figure 3-3-1 Structure of the Human Eye

The retina is neural tissue, with neat layers of cells. The outermost layer of the retina is composed of jet black pigment cells that prevent the reflection of light, and photosensitive cells, which sense light directly, are located just inside the pigment cells. These photosensitive cells are a type of neuron that has been transmuted to be sensitive to light, and there are cones and rods. (Figure 3-3-2) The name of cone is said to derive from cone shape and the name of rod is said to derive from the rod-like shape of the outer segments. There are three types of photosensitive proteins in the cones, which respectively react most sensitively to blue, green, and red lights. Since we perceive final light by combining blue, green, and red information, we humans recognize all colors from purple to crimson using only three cones for blue, green, and red. On the other hand, rods have only one type of photosensitive protein (called rhodopsin, made of vitamin A), which cannot distinguish between different wavelengths but is very sensitive and can perceive even weak light sensitively [2, 5-8].

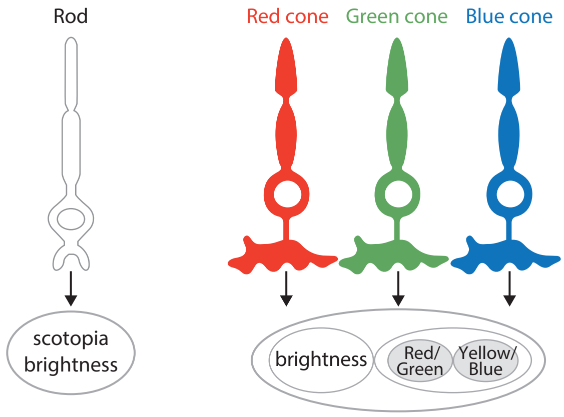


Figure 3-3-2 Photosensitive Cells

These photosensitive cells are distributed in the outer layers of the retina, with approximately 6.5 to 7 million cones and 115 to 120 million rods [2, 8]. In addition, the central retina, which corresponds to the exact center of the visual field and is the most important area of the retina for the development of vision, is called the central retinal fovea. Only the cones are present in high density in the central retinal fovea, and there are no rods. Visual acuity is particularly high only in this region, and is considered weak outside the central fovea. For example, when we gaze at something, we use only the central retinal fovea. On the other hand, the rods are distributed throughout the retina except for the central fovea, and their sensitivity to light is said to be several hundred times higher than that of the cones.

When sufficient brightness is available, the cones are mainly active, and vision at this time is called photopic vision (or cone vision). Conversely, vision in which brightness is insufficient and only the rods are active is called scotopic vision (or rod vision). For example, a red or yellow flower may seem brighter than a green leaf during the daytime, but at dusk, the green leaf may seem brighter. This is due to the different wavelength sensitivity of the cones and rods. In clinical dentistry, it is believed that humans perceive color mainly by the cones, because sufficient brightness is provided by the clinic lighting [2, 5-8].

3.4 Intensity Difference and Visibility

As mentioned above, light entering the eye from the external environment can be perceived as colors by the cones. It is said that the human eye can distinguish approximately 7.5 to 10 million colors, and in order to understand and utilize that many colors, it is necessary to organize and classify colors [9].

These colors can be roughly classified into chromatic colors such as red, yellow, green, and blue, and achromatic colors such as white, gray, and black. In addition, chromatic colors have independent attributes of hue, intensity, and saturation (the three attributes of color), as shown in Figure 3-4-1. Hue is an attribute that expresses the difference in color quality or shade, such as red, yellow, green, blue, etc. Intensity is an attribute that expresses the relative lightness, darkness and brightness of colors, and is determined by the reflectance of an object's surface and other factors. Saturation is an attribute that expresses the intensity of shades and vividness of colors [10, 11].

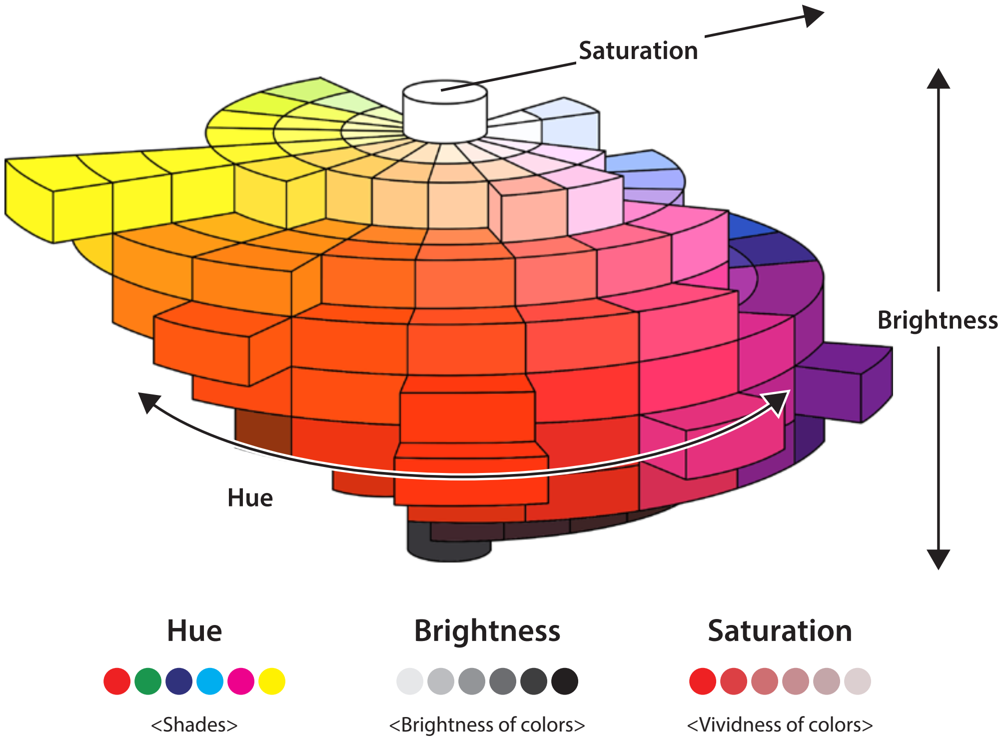


Figure 3-4-1 Three Attributes of Color (Hue, Brightness and Saturation)

In order to better understand how humans perceive colors, it is necessary to consider the interaction between adjacent colors when multiple colors are juxtaposed (contrast phenomenon, Liebmann effect, etc.). For example, in Figure 3-4-2, gray squares of the same intensity are lined up against background colors of different lightness. In this case, the gray squares in the white area appear slightly darker and the gray squares in the black area appear slightly whiter.

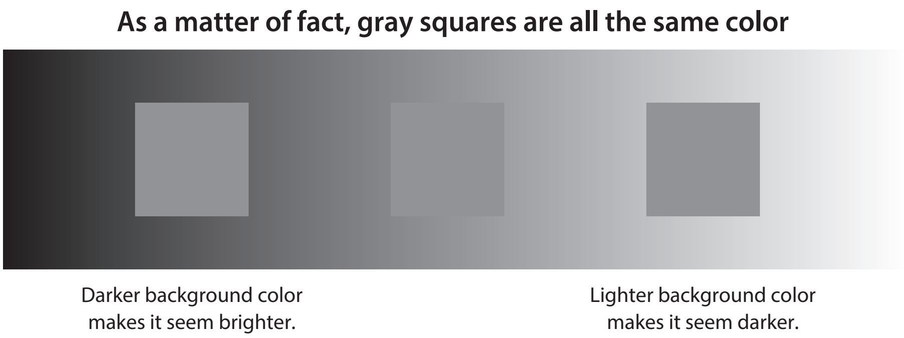


Figure 3-4-2 Color Appearance by Background Color
(Those 3 gray squares are all the same color)

The figure above shows the brightness contrast among the contrast phenomena. In the case of universal shade direct composite resin, the key point is how much the visibility (ease of recognition of the filling) can be lowered when compared to the surrounding tooth substances. For example, on a black background, red and yellow are more easily recognized than blue and purple. Conversely, on a white background, blue and purple are more easily recognized, showing the opposite trend from the case of a black background (Figure 3-4-3). In other words, the difference in brightness between the background and the object is a factor that determines visibility [10, 11].

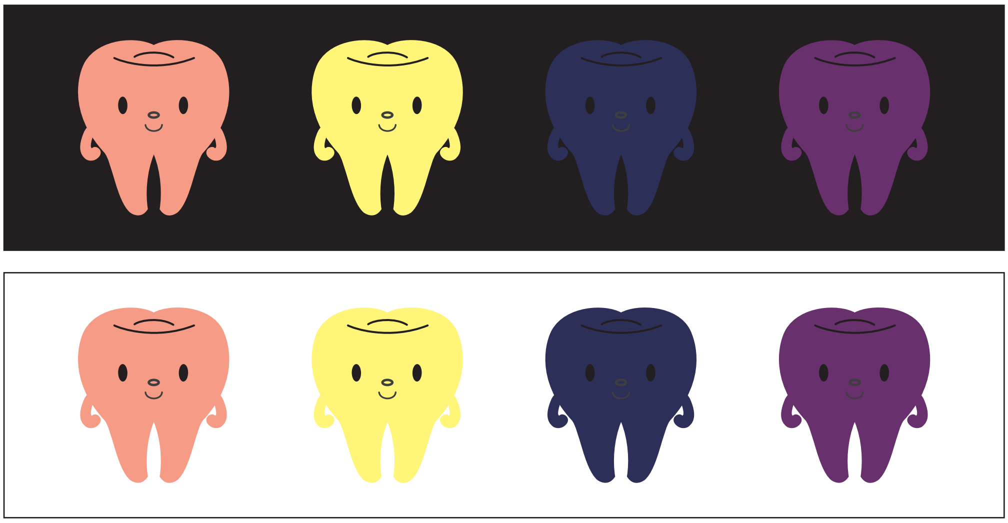


Figure 3-4-3 Change in Color Visibility When Background Color Changes
(corresponding illustrations top and bottom are the same color)

Furthermore, colors with small differences in brightness can give a calm impression to humans and appear to blend well with each other, even if they are very different in hue. Conversely, if there is a great difference in brightness, the contrast increases and visibility is enhanced (Figure 3-4-4). The above phenomenon, in which adjacent colors have a great difference in hue but are close in brightness, causes the boundary to blend and become indistinct and difficult to see, and is known as the Liebmann effect[9-11]. In the design of universal shade direct composite resins, it is considered important to minimize the brightness difference from the tooth substances so that the Liebmann effect is high.

Figure 3-4-4 Colors Perceived according to Brightness Differences
(left: small differences, right: large differences)

3.5 YAMAKIN's Golden Ratio of Transparency, Shielding Property and Intensity

As mentioned above, brightness is the key for a material to blend in with the surrounding tooth substances. Needless to say, the color design of the material itself is important, but considering that natural teeth are translucent materials, transparency and shielding property are also important. This is because the brightness of the direct composite resin will be greatly affected by the background color if it is a Class IV cavity where light passes through from the labial side to the lingual side or if it is a cavity with discoloration at the bottom of the cavity. Intensity, which has not been mentioned much up to this point, must also be taken into consideration because it affects the tonal compatibility when the cavity is large.

In the following explanation of "Camouflage Effect", we break down the color matching technology of A·UNO into the three components: ① Transparency, ② Shielding Property and ③ Intensity.

①Transparency

The transparency of direct composite resin should match the half-transparency of natural teeth, especially in the restoration of Class IV cavities. For example, as shown in Figure 3-5-1, if the direct composite resin has low transparency, the background color is excessively masked, making it difficult to reproduce the transparency of the incisal area. On the contrary, if the transparency is too high, the direct composite resin filling is too affected by the dark background color and is easily visible without blending with the surrounding tooth substances. A·UNO is designed to be applied to Class IV cavities with optimal transparency close to that of natural teeth to reproduce natural color tones.

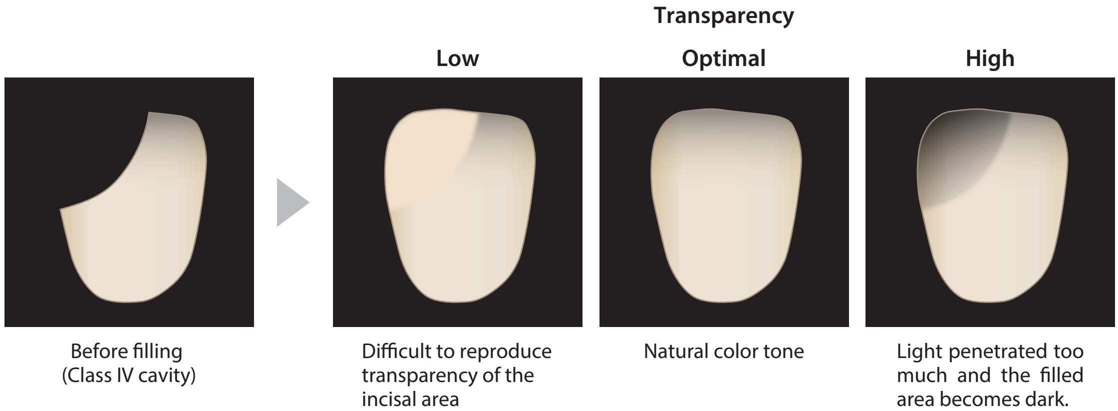


Figure 3-5-1 Image of Cavity Filling of Direct Composite Resin with Different Transparencies

② Shielding Property

As described above, A·UNO has a certain degree of transparency, allowing it to reflect the surrounding color tone of the filling area while also reproducing of transparency at the incisal edge. However, there are cases that cannot be handled simply by absorbing ambient light depending on transparency. For example, if there is discoloration at the bottom of the fossa, this discoloration will be strongly reflected if the direct composite resin has a low shielding property, whereas if the shielding property is too high, it will be hard for the filling part to blend well with the color of the surrounding tooth substances. A·UNO maintains transparency while increasing turbidity, thereby shielding the discoloration at the bottom of the fossa optimally, and reproducing a natural color tone.

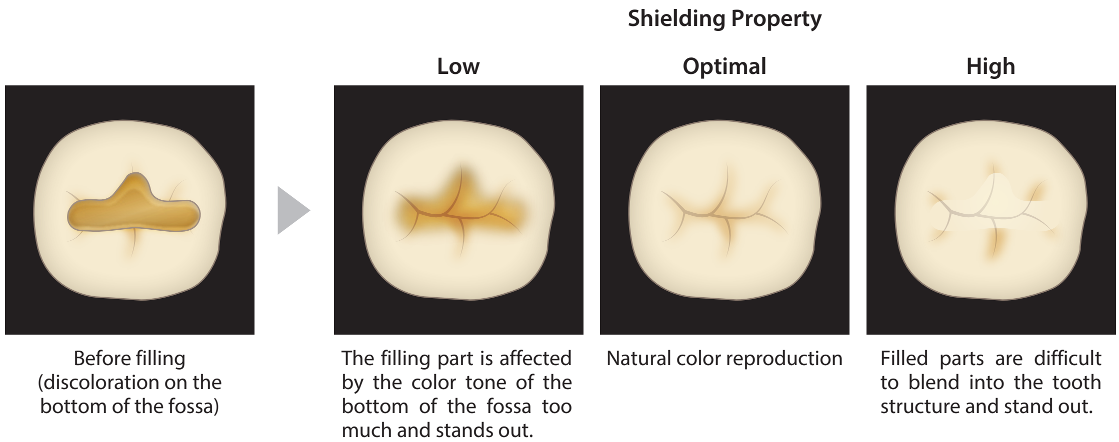


Figure 3-5-2 Images of Filled Cavities with Direct Composite Resins with Different Shielding

③ **Intensity**

There are differences of width or thickness of the indirect composite resin depending on the size of the cavities. In the case of Universal shade direct composite resin, when the cavity is small, the color of the resin itself has little effect on the color tone of the restoration even if its intensity (color depth) is low, because the color tone of the surrounding tooth substances can be taken in. However, when the cavity is large, the intensity of the resin itself greatly affects the color tone of the restoration. In other words, if the intensity of the resin is low (pale color), the larger the cavity, the whiter and brighter the restoration appears, and the filling area is more likely to appear white. Conversely, if the saturation of the resin is high (darker color), the filling area appears darker. (Figure 3-5-3). In order to reduce the influence of the amount of filling on the cavity, A·UNO is colored with a small amount of red and yellow pigments to minimize the change in intensity and brightness with thickness, so that it blends well with cavities of different sizes.

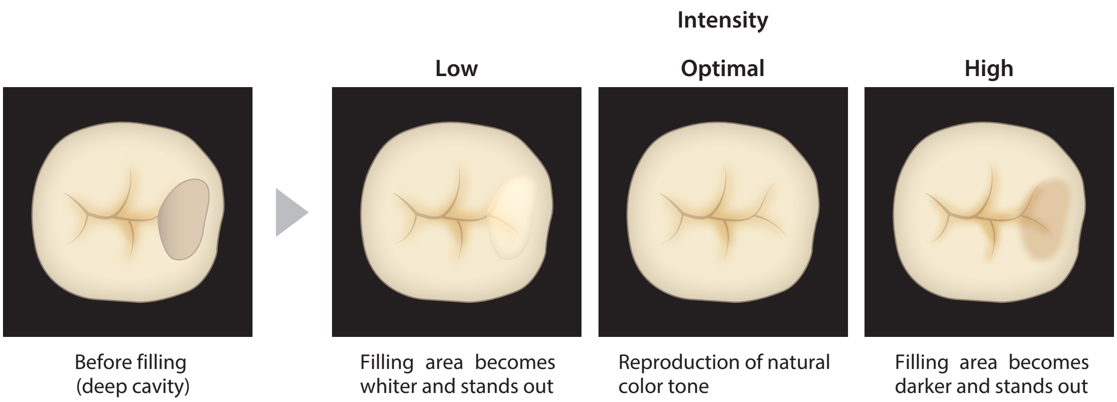


Figure 3-5-3 Images of Cavity Filling with Direct Composite Resins of Different Intensity

As described above, A·UNO is designed to have high light transmission and light diffusivity so that the color tone of the surrounding tooth substances can be easily taken in. At the same time, it also has shielding properties that are less affected by background color by increasing turbidity. Even when the amount of resin filling is large, use coloring to add appropriate intensity to minimize the change in brightness. In other words, A·UNO is a product that optimizes the balance between transparency, shielding property and intensity, based on the concept of using a single color to suit as wide a range of cases as possible.

3.6 Cavity Filling Using A • UNO

1) Class IV cavity model

Because of its optimal transparency and shielding properties, A·UNO can reproduce the natural border between the tooth substances while shielding the background color, and can also express the transparency of the incisal edge.

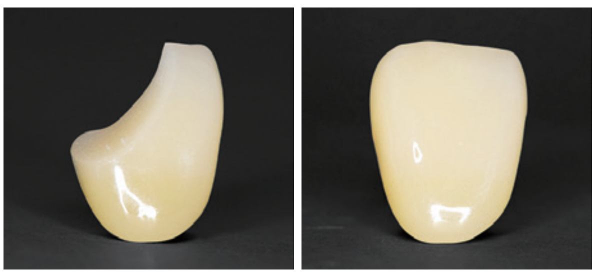


Figure 3-6-1 Class-IV Cavity: Cavity without Backing (Cavity Model : A2)

2) Case model with discoloration at the bottom of the fossa

The natural appearance is reproduced while shielding the discolored area optimally.

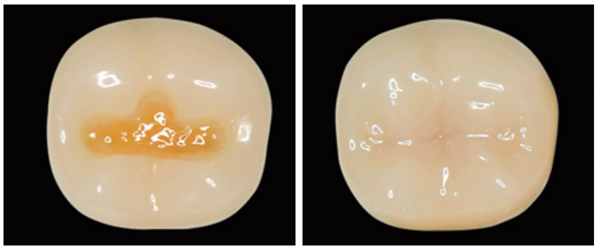


Figure 3-6-2 Class I Cavity with Discoloration at the Bottom of Fossa (Cavity Model: A3)

3) Case model with MTA cement in the bottom of fossa

After applying TMR-MTA cement Mielle (white) to the bottom of fossa, A·UNO was filled in to reproduce a natural appearance while shielding the white color of the MTA cement.

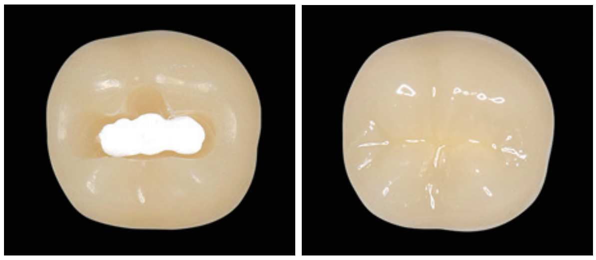


Figure 3-6-3 Class I Cavity with MTA Cement at the Bottom of the Cavity (Cavity Model: A3)

4) Class II cavity model vith adjacent metal tooth

Thanks to the optimal shielding property and intensity of A·UNO, which reduces the influence of the gray color of the metal and reproduces a natural tooth color tone without too much whitish color, even in deep cavities.

Figure 3-6-4 Class II Cavity Deep Cavity with Adjacent Metal Tooth (Cavity Model: A3)

So far, we have shown models of cases for which a single A·UNO syringe application is enough. However, in some cases, using only one A·UNO is esthetically difficult. For example, dark-colored aged teeth, whitened bright teeth, etc. may be considered. In such cases, the use of a darker shade (such as A5 or OA5) or a white shade (such as BW or OW) of TMR-Z Fill 10. as a base shade can provide a more esthetic restoration.
Also, care should also be taken in cases where the majority of the crown is formed using only one shade of A·UNO. As explained in section 3.1, the Camouflage Effect of A·UNO assumes the presence of tooth color in the surrounding area. Therefore, in cases where there is no tooth substance to serve as a base for color, TMR-Z Fill 10. should be used as the base color of the crown.

3.7 Two Types Can Be Chosen According to Clinical Scenes and Doctor's Preferences

There are two types of A·UNO lineup; Normal Type that changes color (transparency) before and after light curing, and St Type (Steady Transparent) that hardly changes color (transparency) at all.
Normal Type and St Type can be chosen depending on clinical cases or doctor's preference (Table 3-7-1).

Table 3-7-1 Characteristics of Normal Type and St Type

	Characteristics	Merit
Normal Type	Before curing, the transparency is lower than that of the tooth substances. Therefore, the filling area is highly visible.	• Because the boundary between the filling and tooth substances is easy to see, the morphological treatment process can be done easily. • Transparency changes before and after curing. Therefore, the completion of light curing can be confirmed visually.
St Type	Almost no change in transparency before and after curing.	• It is possible to imagine the color tone after treatment at the time of filling.

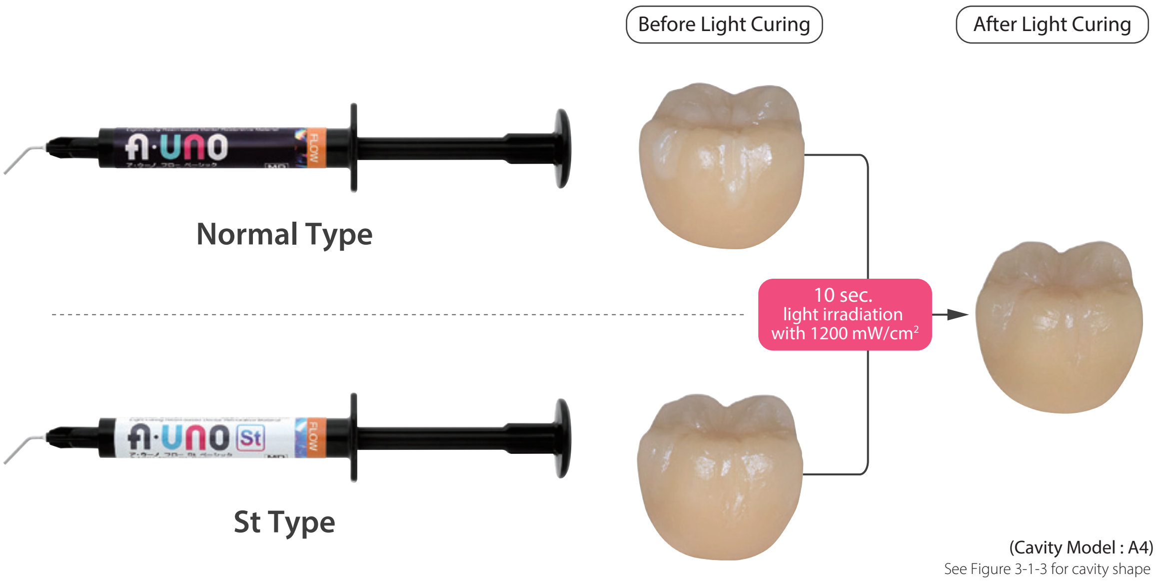


Figure 3-7-1 Color Tone of Normal Type and St Type before and after Light Curing

The filler components and composition ratios are basically the same for the Normal Type and St Type. Nevertheless, the reason for the large differences in color change behavior before and after curing is that the monomer components and their composition ratios described in Section 2.1 are unique. The important physical property here is the refractive index. The refractive index is a physical quantity unique to a material that affects the speed of light in the material and is expressed as "the speed of light propagation in a vacuum / the speed of light propagation in the material" [12)]. In organic-inorganic composite materials such as composite resins, transparency is determined by the magnitude of the difference in refractive index between the matrix as the organic component and the filler as the inorganic component. In other words, if the refractive index difference between the matrix and filler is large, light scatters at the interface, resulting in low transparency, and if the refractive index difference is small, transparency is high. There is a scientific experiment called the "disappearing cup," in which a small glass cup is placed inside a larger glass cup, and when salad oil is poured into the glass cup, the smaller glass cup inside disappears. Since the refractive index of glass and salad oil are almost the same, light is not scattered at the interface and becomes transparent, making the small glass cup inside invisible.

In other words, to increase the transparency of the composite resin, it must be designed to have a close refractive index to prevent light from scattering at the interface between the matrix and filler. In the case of composite resins, it is necessary to design the material considering not only that, but also that when the monomer of the matrix is converted into a polymer by photopolymerization, the density increases due to shrinkage and the refractive index increases. Normal Type is designed so that the monomer refractive index is lower than that of the filler before polymerization and the refractive index of the polymer after polymerization is close to that of the filler. St Type is designed so that the refractive index of the filler is adjusted to be between that of the monomer and polymer of the matrix, so that the difference in refractive index between the matrix and filler before and after polymerization is stable and light transmission does not change before and after polymerization.

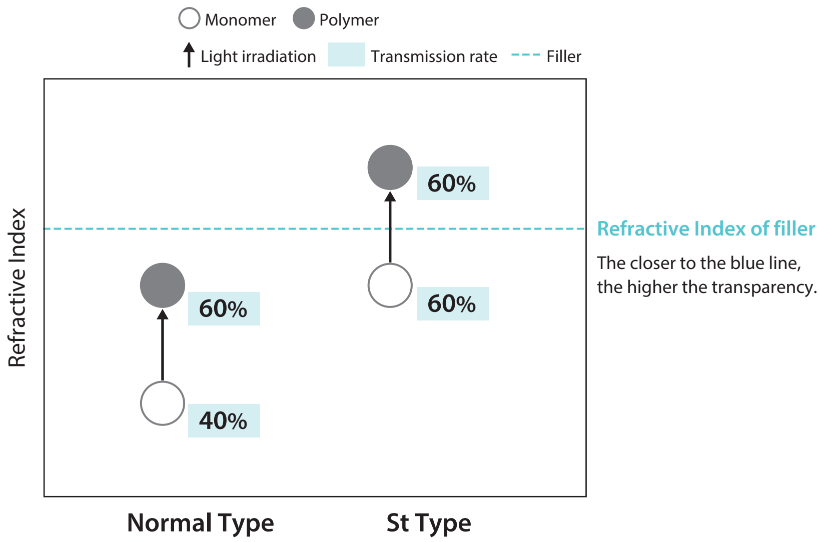


Figure 3-7-2 Image of the Refractive Index of Matrix-filler of Normal Type and St Type

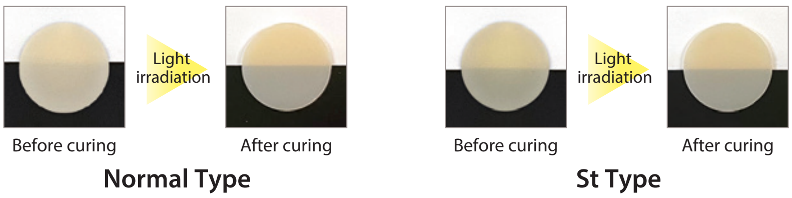
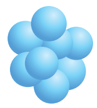


Figure 3-7-3 Color Tone Change before and after Light Curing of Normal Type and St Type

3.8 Higher Functionality through Maximum Utilization of Filler Technology

"KZR-CAD HR Block 2", a hybrid resin block for resin material for dental milling and machining launched in September 2015, achieves both "strength" and "fluoride release", which were previously thought to be difficult to achieve at the same time. This technology has also been applied to "iGOS", a direct composite resin for dental restorative material launched in February 2016, and "TMR-Z Fill 10.", which is launched in September 2018. By utilizing the filler technology developed by YAMAKIN to achieve both "strength" and "fluoride release", as well as by incorporating YAMAKIN's exclusive color-matching technology, the finished product, A·UNO - a Universal Shade type composite resin, was launched in June 2022.

Table 3-8-1 Filler technologies utilized in A • UNO

Shape	Filler	Function	Actual use in YAMAKIN's resin products
	Ceramics Cluster Filler (C.C.F.) (2-8 μm)	Improved mechanical strength Improved abrasion resistance Formability Improved polishability	・KZR-CAD HR Block series ・TWiNY ・TMR-Z Fill 10.
	Fluoride Sustained Release Filler (700 nm)	Fluoride sustained release property Fluoride recharge property	・KZR-CAD HR Block series ・TMR-Z Fill 10.
	Spherical Nano-Filler (20 nm)	Improved mechanical strength Improved handleability	・KZR-CAD HR Block series ・Luna-Wing ・TWiNY ・TMR-Z Fill 10.
	Spherical Nano-Filler (50 nm)	Improved filling rate Improved abrasion resistance	—

As shown in Table 3-8-1, Ceramics Cluster Filler (C.C.F.), which are essential for improving mechanical strength and formability, are cluster fillers that primarily comprize particles (submicron fillers of 200-600 nm) of silica-zirconia-alumina composite oxides synthesized by the sol-gel method, granulated to 2-8 μm by firing and milling, and having an uneven surface. Moreover, to improve mechanical strength and handleability, there are Spherical Nano-Filler particles of about 20 nm, Fluoride Sustained Release Filler to provide fluoride-releasing and fluoride-recharging properties, and Spherical Nano-Filler particles of about 50 nm to improve filler filling rate and abrasion resistance. Those fillers are used in combination according to the product concept for each product.

A·UNO is the culmination of all the filler technologies that YAMAKIN has accumulated in its resin products to date.

COLUMN

Derivation of the product name "A•UNO"

"A" means "one" in English and "UNO" means "one" in Italian and Spanish. In other words, the concept of covering 16 shades with "ONE shade" is incorporated into the product name.

"Auno" in Japanese means "matching". This is from the fact that A•UNO matches the color tone of the tooth substances. The development of this product started as the "All A•UNO Project" based on the concept of matching all tooth colors. However, in clinical practice, there were cases with very dark shades such as A5 shade, and pure white teeth that had been whitened, in addition to 16 shades. Therefore, it was found that it would be difficult to match all natural tooth colors with only one color. For that reason, The product name was decided as A•UNO.

There is a world-famous card game called "UNO", in which if a player forgets to declare "UNO" when he or she has only one card in hand, he or she must draw two cards from the rest of the cards when another player points out "Oh, you didn't say UNO!" The colors of UNO cards are red, green, blue, and yellow, which are also known as the four primary colors. A•UNO has only Basic Shade, and the name of this shade reflects our wish that this shade is used as the basic color for tooth substances.

A·UNO

4 Characteristics of A•UNO

4.1 Handleability

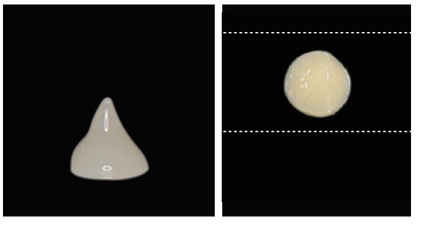
1) Flowability

A·UNO is available in three types of pastes: Universal, which is less sticky and has excellent formability; Low Flow, which has optimal viscosity and can be poured into the cavity without dripping; and Flow, which has high fluidity and can flow into the cavity. The use of these types for different cases and on different filling sites can shorten the working time.

15 min. after shaping (Horizontal)

Figure 4-1-1 Universal Type Paste Properties

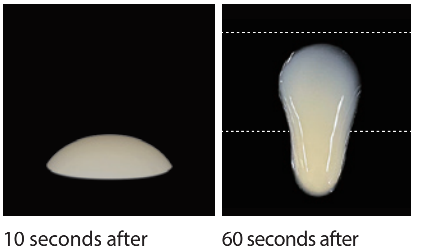
Universal type adheres adequately to the tooth structure and prevents air bubbles from being entrapped during filling, and is not sticky. Universal type also has excellent morphogenetic stability and does not drip after applying, allowing for delicate filling work such as occlusal morphology (Figure 4-1-1).



10 seconds after having been taken out (Horizontal) | 60 seconds after having been taken out (Vertical/0.5g)

Figure 4-1-2 Low Flow Type Paste Properties

As shown in Figure 4-1-2, Low Flow type has optimal viscosity, displaying both fluidity and the ability to form a shape. This optimal viscosity is expected to allow the product to be used in a wider range of cases.



10 seconds after having been taken out (Horizontal) | 60 seconds after having been taken out (Vertical/0.5g)

Figure 4-1-3 Flow Type Paste Properties

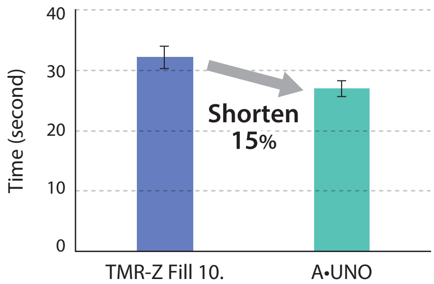
As shown in Figure 4-1-3, the paste of Flow type flows and spreads quickly after having taken out, and this high fluidity allows it to easily flow into the cavity and quickly stick to the tooth substances. Suitable for filling of small cavities and lining.

2) Polishability

Sufficiently polishing and smoothing the surface reduces the adhesion of plaque to direct composite resins. In order to minimize the burden on the patient in composite resin restorations, polishing must be completed in a short period of time.

A･UNO is designed to be easily polished despite its high filler content by maximizing the use of YAMAKIN's filler technology. In addition, the ratio of fine filler is higher than that of the existing composite resin TMR-Z Fill 10., which makes it easier and quicker to obtain gloss (Figure 4-1-4).

Appearance of A•UNO crown before and after polish



Time necessary for polish

(Test method : In-House Test)
Polished resin surfaces equivalent to 5 mm diameter

Figure 4-1-4 Polishability Evaluation (Universal Basic)

3) Improvement of syringes

In direct composite resin restorations, air bubbles in the filled resin must be avoided because they cause postoperative defects (reduced strength and esthetics). Therefore, A･UNO investigated the cause of air bubbles inside the syringe and improved the design of the syringe's internal shape to significantly reduce the entrapping of air bubbles (Figure 4-1-5).

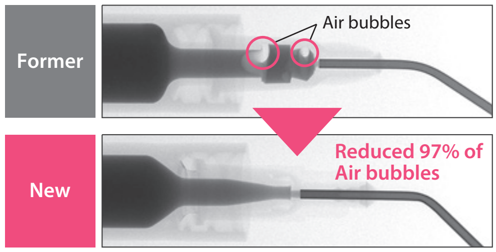


Figure 4-1-5 Improvement of Syringe Design

4.2 Mechanical Properties

1) Flexural strength

The flexural strength of A･UNO was evaluated by a three-point bending test in accordance with JIS T 6514 [13]. A･UNO was filled into a 2 mm × 2 mm × 25 mm mold, light-cured, and prepared with water-resistant abrasive paper to make test specimens. The specimens were stored in water at 37 °C for one day and then, measured using a compact table-top tester. (EZ-Graph: Shimadzu Corporation). The thermal cycle test is used to evaluate the durability of the material by alternately immersing the specimens in hot and cold water to promote material degradation, utilizing the difference in thermal expansion coefficient of the constituent materials in the material. This test is a model test assuming use in the oral cavity. In this test, the material was immersed at 4 °C and 60 °C for 60 seconds each for 5,000 cycles, followed by a three-point bending test to confirm durability (Figure 4-2-1). The flexural strength of A･UNO is equivalent or superior to that of our existing product, "TMR-Z Fill 10." and the value after thermal cycling is improved. The surface treatment conditions (silane coupling agent and treatment method) of the inorganic filler have been improved in A･UNO, and it is assumed that this has improved the water resistance. The improved surface treatment conditions increased the filler filling ratio of A･UNO by 3 to 4 %, from TMR-Z Fill 10. Universal (77 wt%) and Flow (67 wt%) to A･UNO Universal (81 wt%) and Flow (70 wt%). Universal and Flow types of A･UNO showed similar durability. Therefore, the doctor can freely select the preferable paste type for the application case without considering the difference in durability.

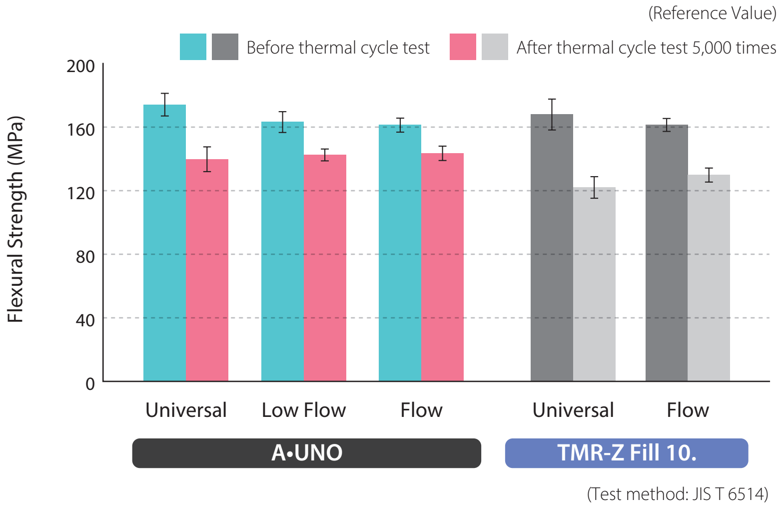


Figure 4-2-1 Flexural Strength

2) Abrasion resistance

Dental restorations repeatedly come into contact with the opposing teeth through occlusion, causing abrasion to the natural teeth and the restoration itself. If the amount of abrasion is too large, the occlusal balance will be upset and the bite will be deteriorated. Therefore, abrasion resistance to the opposing teeth is an important performance. Consequently, an opposing teeth test was conducted to evaluate abrasion resistance. The test method was an impact abrasion test under 37 °C water, in which a model of an opposing teeth using a bovine tooth was impacted with a load of 5.8 kgf against a pellet-shaped test specimen, and the cycle of moving the model left and right by 1 mm was repeated 50,000 times (Figure 4-2-2). This test was conducted using bovine tooth enamel (320 HV)[15] with Vickers hardness close to that of natural human teeth (300-350 HV)[14]. As shown in Figure 4-2-3, A·UNO has improved abrasion resistance compared to the existing product TMR-Z FiIl 10. due to its dense and high filling of four types of inorganic fillers. Furthermore, the amount of abrasion on the impact-worn counterparts was significantly lower than that of impact wear between bovine tooth enamel, indicating that this material suppresses the risk of tooth abrasion on the occlusal parts.

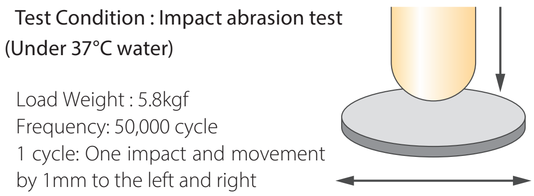


Figure 4-2-2 Schematic Diagram of the Opposing Teeth Abrasion Test

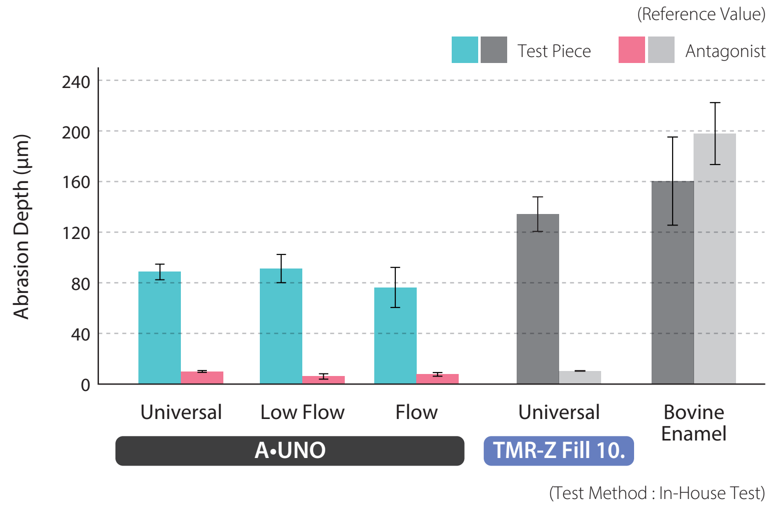


Figure 4-2-3 Abrasion Test of Opposing Teeth

4.3 Fluoride sustained release property

1) The Amount of Fluoride Ion Release

Fluoride ions taken into the oral cavity are known to inhibit enamel demineralization, promote remineralization and exhibit caries-preventive effects[16-20]. A·UNO contains fluoride sustained release fillers expecting these effects. The fluoride sustained release property of A·UNO was evaluated as follows. A·UNO was filled into a mold with a diameter of 12 mm and a thickness of 0.5 mm, light cured by a light curing machine, and the surface of the cured specimen was prepared with water-resistant abrasive paper. The prepared specimens were thoroughly rinsed under running water and immersed in 15 mL of distilled water. After a predetermined period of time, the specimens were removed and the fluoride ion concentration in the immersion water was measured with an ion meter (F-55: HORIBA, Ltd.). The fluoride ion release per unit area was then calculated. The measurement results (Figure 4-3-1) show that A·UNO releases fluoride ions stably for more than 6 months.

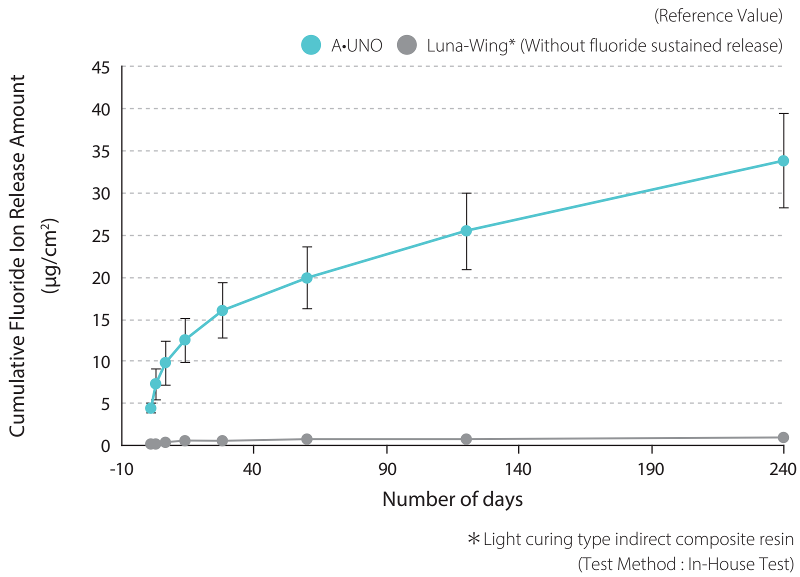


Figure 4-3-1 Fluoride Sustained Release Property

2) Fluoride recharge property

The fluoride sustained release filler used in A·UNO can recharge fluoride ions when brushing with a fluoride-containing toothpaste. The following model experiments were conducted to verify this.

A 15 mm diameter, 0.5 mm thick mold was filled with a resin material containing fluoride sustained release filler, which is also contained in A･UNO, and light cured. And the surface of specimen after light curing was prepared with water-resistant abrasive paper. The specimens were immersed in 15 mL of distilled water for a total of 48 hours to release fluoride ions to some extent. After fluoride ion release, the specimens were brushed using a simple toothbrush abrasion tester based on ISO 14569-1 [21]. The specimens were fixed in fluoride toothpaste liquid and brushed 500 times with a toothbrush at a load of 2.0 N and a sliding speed of 850 mm/s. After brushing, the specimens were thoroughly rinsed under running water, and the amount of fluoride ions released from the specimens was measured with an ion meter. Brushing and fluoride ion measurement were performed four times in total. From the measured fluoride ion content, it was confirmed that brushing with fluoride-containing dentifrice showed fluoride rechargeability (Figure 4-3-2). The amount of fluoride ions released remained stable even after repeated recharging, suggesting that the fluoride rechargeability is highly repeatable. In other words, if fluoride sustained release filler is used in direct composite resins that are maintained in the oral cavity for several years or more, it can be expected to exhibit semi-permanent fluoride release properties through regular brushing. On the other hand, no recharge behavior was observed in the same experiment using a resin material without a fluoride sustained release filler, indicating that this property is derived from the fluoride sustained release filler also used in A･UNO.

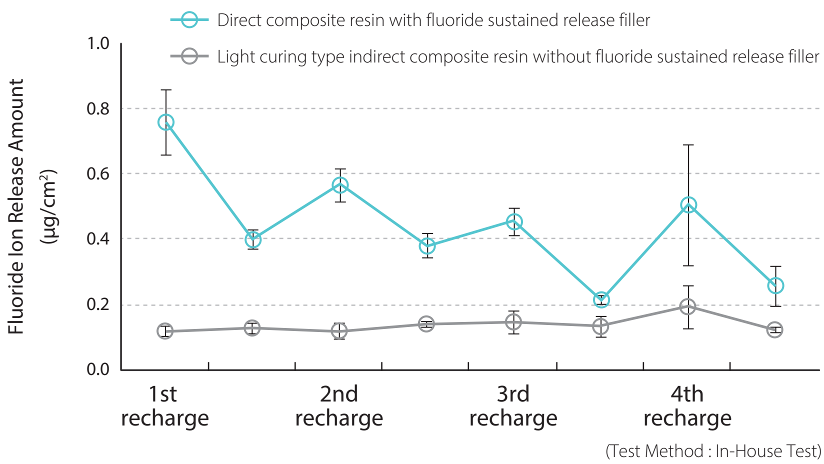


Figure 4-3-2 Amount of Fluoride Ion Release during Brushing with Fluoride-containing Dentifrice

3) Effects on caries bacteria

Various caries-preventive functions of fluoride ions have been reported [22-24]. As described supra, A･UNO has long-term fluoride release property and recharging properties. In this section, the effects of A･UNO, which has a low fluoride release rate, on *Streptococcus mutans* (hereafter referred to as "caries bacteria") were examined using the propagation, adhesion, and acid production of the bacteria as indicators. Molds of 12 mm in diameter and 1.0 mm in thickness were filled with Universal type of A･UNO, light cured by light curing machine, and the surfaces were prepared with water-resistant abrasive paper to make specimens. As a comparison, the existing product TMR-Z Fill 10. and Luna-Wing which is light curing type indirect composite resin without fluoride release property were used as control samples.

• Proliferative study

Resin extracts were prepared by adding 1 mL of BHI liquid medium per specimen and immersing the specimens in the medium for 24 hours at 37 °C. Caries bacteria were cultured in each resin extract, and the absorbance at 590 nm was measured 24 hours after the start of culture. The higher the number of bacteria, the more turbid the culture medium becomes, which is reflected in the absorbance, and the absorbance decreases when propagation is inhibited. As shown in Figure 4-3-3, there was no decrease in absorbance for any of the light curing type indirect composite resins which are without fluoride release property.

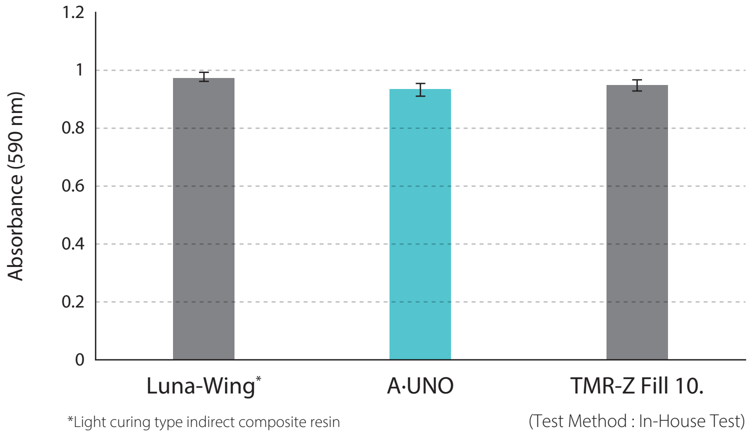


Figure 4-3-3 Propagation Test of Caries Bacteria

• Adherence test

Caries bacteria were cultured aerobically in BHI liquid medium with sucrose for 24 hours at 37 °C on each resin specimen. Washed with PBS (-), and then colored for 2 hours after the addition of test solution of MicrobialViabilityAssayKit-WST (DOJINDO LABORATORIES) [25], and measured the absorbance of the reaction solution at 450 nm. In this test, orange-colored formazan was produced due to the caries bacteria remaining on the specimen. Therefore, the smaller the number of bacteria adherence to the material, the paler the orange coloration (lower absorbance). As shown in Figure 4-3-4, a large decrease in absorbance was observed for A·UNO, which has a higher fluoride release amount than the existing product, and TMR-Z Fill 10., which is a existing product, unlike the light curing type indirect composite resin without fluoride release.

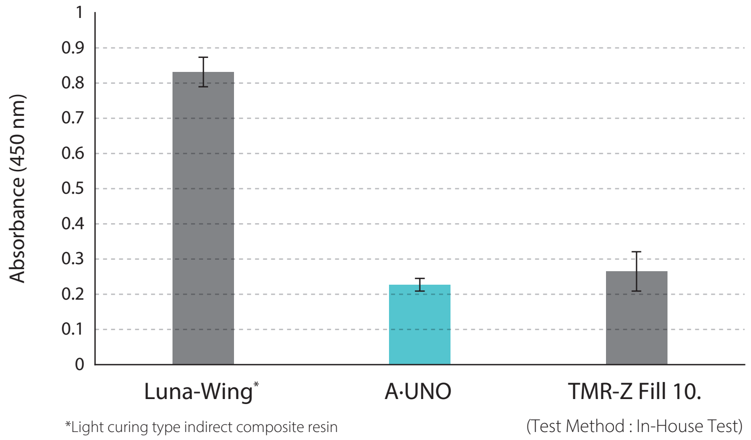


Figure 4-3-4 Bacteria Adherence Test

• Lactic acid production test

The amount of lactic acid produced by caries bacteria was measured using the Lactate Assay Kit-WST (DOJINDO LABORATORIES). In this measurement method, lactate in the bacterial nutrient solution is detected by absorbance measurement of WST formazan, which develops a color in accordance with the amount of lactate. If lactate production decreases, absorbance also decreases. Caries bacteria were cultured in each resin extract, the culture medium was centrifuged, and the supernatant was collected. After adding WST reagent to the supernatant, it was left to stand at 37 °C for 2 hours, and absorbance was measured at a wavelength of 450 nm. As shown in Figure 4-3-5, the absorbance of A·UNO and TMR-Z FiIl 10. was lower than that of the control sample.

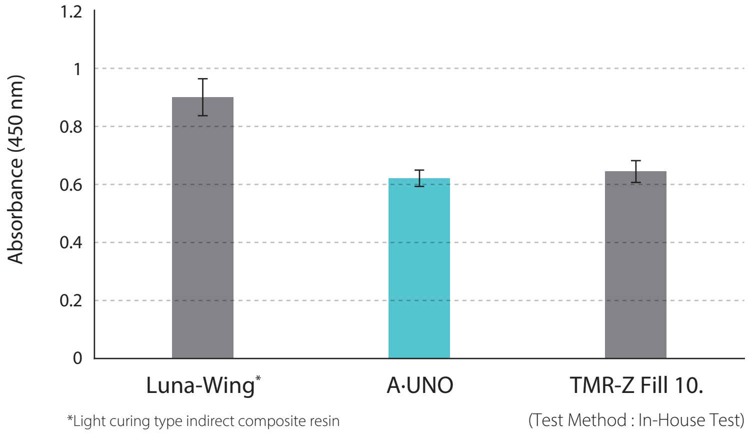


Figure 4-3-5 Caries Bacteria Lactic Acid Production Test

Further validation of the above test results revealed that A·UNO and TMR-Z Fill 10. showed Enolase inhibition. Since Enolase is an enzyme in the glycolytic system related to lactic acid production, inhibition of Enolase in the bacteria is thought to have led to inhibition of lactic acid production [26].

4) Risks of fluoride ions

Fluoride has various properties related to the prevention of dental caries, but there are reports on the risks associated with fluoride occasionally. Excessive fluoride ingestion causes acute poisoning, while high concentrations taken over a long period of time cause chronic poisoning. In Japan, the threshold for acute poisoning has been set at 2 mg F/kg based on Baldwin's report[27]. Fluorosis is another symptom of chronic poisoning. An epidemiological study by Dean et al. showed that fluorosis formation begins in areas where the fluoride concentration in drinking water exceeds 0.4 ppm, and that esthetically problematic fluorosis which is medium degree or more occurs at around 2.0 ppm. The incidence of fluorosis is relatively low at fluoride concentrations of around 1.0 ppm, and caries are also reported to be less common at this level [28].

In addition to the effects on the human body such as fluorosis, fluoride has been reported to cause corrosion of the pure titanium or titanium alloys used for dental implants. The details are discussed in the book "Biocompatibility of dental materials"[29]. Fluoride-induced corrosion of titanium tends to occur under high fluoride concentrations, acidic conditions, and hypoxic conditions. However, the risk of fluoride-induced corrosion of titanium prosthetics in the oral cavity is considered low because most fluoride products currently in use are used in neutral environments, and saliva in the oral cavity buffers against low fluoride concentrations and acidic environments. The daily fluoride ion release of A·UNO is 4.5 μg/cm^2 (Universal type), which is very low compared to the fluoride concentration in tooth coating agents and dentifrices, so the possibility of titanium corrosion is considered to be extremely low.

4.4 Biological Safety

When a dental material comes into contact with the human body, even slightly, a biological safety assessment is required. A biological safety assessment is an evaluation of the risk of adverse effects on human health. Marketing is authorized when a biological safety assessment demonstrates that there is no risk or that the risk is acceptable. The biological safety evaluation items to be considered for dental materials vary widely depending on the characteristics of the dental material. As shown in Table 4-4-1, the classification is based on the site of contact with the body (surface-contact medical devices, intra- and extra-corporeal contact medical devices, and implantable devices) and the contact period (temporary contact, short to medium term contact, and long-term contact). Since A·UNO is used in the oral cavity, it is naturally a medical device that comes into contact with humans. Biological safety evaluation is required, and the device falls into the category of "medical devices that connect the inside of the body to the outside of the body, long-term contact. "A·UNO" is composed only of raw materials whose safety as a medical device has been confirmed through the necessary biological safety evaluation.

All of the above biological tests were conducted in collaboration with the Department of Oral and Maxillofacial Surgery, Kochi Medical School, Kochi University, Japan.

Table 4-4-1 Endpoints to be addressed in a biological risk assessment for dental materials

Contact duration (accumulation): A-limited(≦24h), B-prolonged (>24h to 30 days), C-Long term (>30 days)			Endpoints of biological evaluation														
			Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity	Acute systemic toxicity	Subacute toxicity	Subchronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive/developmental toxicity	Degradation
Non-contact medical devices			None of the evaluations are required														
Surface medical device	Intact skin	A	×	E	E	E											
		B	×	E	E	E											
		C	×	E	E	E											
	Mucosal membrane	A	×	E	E	E											
		B	×	E	E	E		E	E			E					
		C	×	E	E	E		E	E	E	E	E		E			
	Breached or compromised surface	A	×	E	E	E	E	E									
		B	×	E	E	E	E	E	E			E					
		C	×	E	E	E	E	E	E	E	E	E		E	E		
Externally communicating medical device	Blood path, indirect	A	×	E	E	E	E	E					E				
		B	×	E	E	E	E	E	E				E				
		C	×	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/bone/dentine	A	×	E	E	E	E	E									
		B	×	E	E	E	E	E	E			E		E			
		C	×	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	×	E	E	E	E	E					E	E			
		B	×	E	E	E	E	E	E			E	E	E			
		C	×	E	E	E	E	E	E	E	E	E	E	E	E		
Implant medical device	Tissue/bone	A	×	E	E	E	E	E									
		B	×	E	E	E	E	E	E			E		E			
		C	×	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	×	E	E	E	E	E				E	E	E			
		B	×	E	E	E	E	E	E			E	E	E			
		C	×	E	E	E	E	E	E	E	E	E	E	E	E		

E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

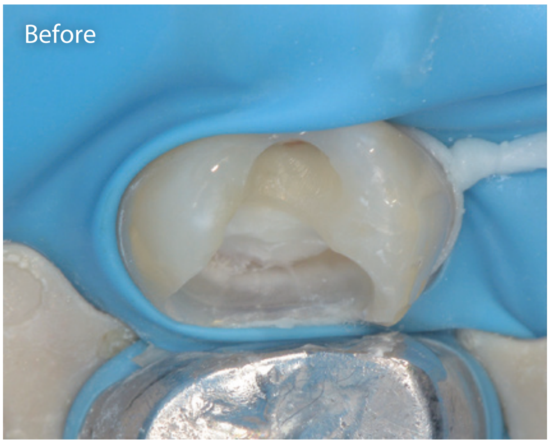
5 Clinical cases of A・UNO

The following are examples of cases in which A·UNO was used. In the case of a median diastema with no backing or having adjacent teeth made of metal, A·UNO can provide transparency at the incisal edge while shielding the color of the backing and the bottom color of tooth, and reproduces a color tone that blends well with the tooth substances. In large cavities with darker tones at the bottom of the fossa, A·UNO was confirmed to match the color tone of the surrounding tooth substances while shielding it optimally. For more esthetic appearance, Nu:le Coat can be used to enhance the color tone reproduction of natural teeth by characterization. A·UNO has also been confirmed to have excellent color compatibility in sealing access holes. The clinical examples below are only a part of the process of direct composite resin restorations using A·UNO. The electronic instructions for use should be referred to.

■ A case of repaired median diastema (Treated after whitening)

Photos provided by : Takeuchi Dental Clinic (Utazu-cho, Kagawa Prefecture, Japan); Dr. Kazutaka Takeuchi)

■A case of repaired Class II cavity (bottom of fossa : TMR-MTA cement Mielle is applied)

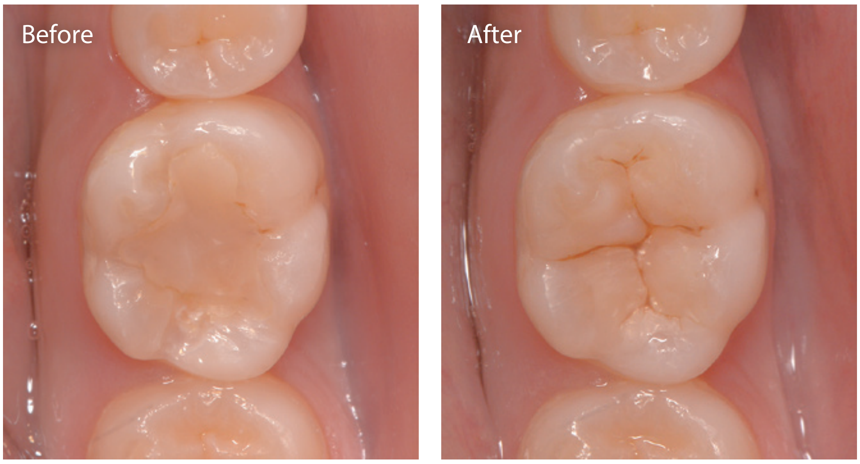


Photos provided by : Takeuchi Dental Clinic (Utazu-cho, Kagawa Prefecture, Japan); Dr. Kazutaka Takeuchi)

■ **A case of repaired Class I cavity (A large cavity with darker color of bottom of fossa)**

Photos provided by: Yamakita Dental Office (Konan City, Kochi prefecture, Japan); Dr. Mayo Yamamoto

■ **A case of repaired Class I cavity (Characterized pit and fissure with Nu:le Coat)**



Photos provided by : Takeuchi Dental Clinic (Utazu-cho, Kagawa Prefecture, Japan);
Dr. Kazutaka Takeuchi)

■ **A case of sealing an access hole (A crown with ceramic layering on a zirconia frame. Characterized pit and fissure with Nu:le Coat)**

Photos provided by : Takeuchi Dental Clinic (Utazu-cho, Kagawa Prefecture, Japan);
Dr. Kazutaka Takeuchi)

Use with Existing Direct Composite Resins

As described in Section 3.6, for teeth with a shade darker than the general shade guide (A4), it is necessary to use a existing direct composite resin such as A5 shade of TMR-Z Fill 10. First, the root surface of the maxillary right central incisor, shown below, was repaired only with TMR-Z Fill 10. Flow A5 shade because the color intensity was very high. On the other hand, the incisal of maxillary right central incisor was repaired with A·UNO, but the color matching was not sufficient, and the repaired area looked whitish. In this case, it is considered that it is possible to reproduce the natural color tone by filling the dentin portion with a direct composite resin with high color intensity before building up the enamel with A·UNO.

■ A case of repaired Class IV cavity which root caries (old age teeth) was repaired

Photos provided by : Takeuchi Dental Clinic (Utazu-cho, Kagawa Prefecture, Japan); Dr. Kazutaka Takeuchi)

6 Conclusion

iGOS, a direct composite resin for dental filling with both "Strength" and "Sustained fluoride release", which were previously thought to be difficult to achieve simultaneously, was created as a result of YAMAKIN's research and development. Building on the advantages of iGOS, YAMAKIN has developed TMR-Z Fill 10., which has good handleability and color tone in clinical practice. However, YAMAKIN's research and development did not stop there, and by maximizing the use of filler technology to achieve both high strength and fluoride release, as well as by incorporating the "Camouflage Effect", a color matching technology developed by YAMAKIN, transparency, shielding property, and intensity were optimized, resulting in the new Universal shade type direct composite resin A·UNO that blends with the surrounding color tones of a wide range of cases with a single color.

We hope that this product, which is based on the concept of MI, will be used to improve patient satisfaction in the mission of preserving one's own teeth with as few extractions and drill as possible. We will continue to develop new products and services in the hopes that we can, even in tiny ways, make a contribution to community healthcare.

The authors

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