SCIENTIFIC PRODUCT INFORMATION

CLEARFIL MAJESTY™ Esthetic
CLEARFIL MAJESTY™ Posterior
CLEARFIL MAJESTY™ Flow

SCIENTIFIC PRODUCT INFORMATION

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1. INTRODUCTION

Composite resins have played an important role in recent progress made in the field of dental restorative materials. This is probably because their material characteristics have improved substantially. These improvements include ease of handling, improved esthetics, greater durability (making it possible to use the materials for posterior teeth), and greater reliability (attained in combination with technological advances in bonding agents).

Currently, the filler loading in composite resins used in dentistry is approximately 80 wt%. This is much higher than the filler loading of composite materials used in the general industry. For this reason, some design creativity is required to develop a composite resin that will meet a range of prescribed properties.

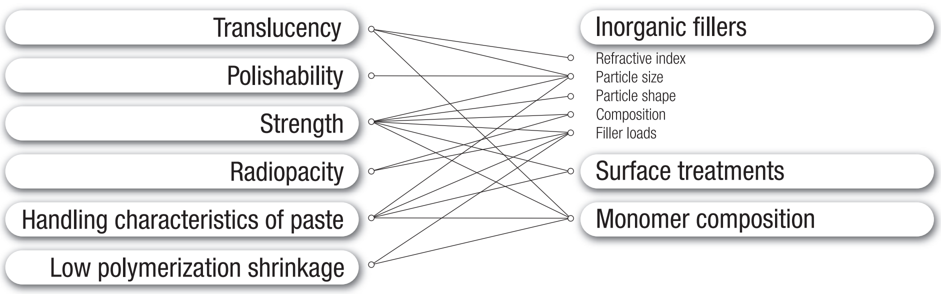
In this report, we will briefly survey the properties required of today's dental composite resins. After that, we will introduce several approaches on how to achieve these properties, including the types of fillers used and the methods of using them, citing some publicly available patent information and the results of academic reports. Finally, we will explain the technological background against which Kuraray's composite resins have been developed, and discuss three new types of composite resin materials we have recently developed.

2. PROPERTIES THAT DENTAL RESTORATIVE MATERIALS SHOULD POSSESS AND THE TECHNOLOGIES NEEDED TO ACHIEVE THEM

Fig. 1 shows the relationship between clinically required properties of dental materials and the technologies needed to achieve these properties. These data are a compilation of information available today from patents and academic papers. Although some researchers might not agree completely with this summary, in general, the development of composite resins is conducted on the basis of these kinds of relationships.

Now, we will explain the approaches used to achieve the properties shown in this diagram.

Fig. 1
Relationship between the properties required of composite resin and the technologies required to achieve them.



TRANSLUCENCY

Translucency is a very important property of composite resins, in terms of esthetics. Reduction in translucency seems to occur mainly due to light scattering at the interface between the filler and matrix monomer, if the filler itself is sufficiently transparent.

We investigated changes after hardening in the translucency of composite resins containing fillers with an average particle size of about 10 µm, by changing the composition of the matrix monomer, shifting the refractive index step by step. *Fig. 2* shows the result of this experiment. The percentage of filler in this composite resin was 50 wt%. Translucency was calculated by first measuring the chromaticity of a 1-mm thick hardened composite resin plate and then subtracting the difference in brightness against a black background from the difference in brightness measured against a white background.

It was found that the composite resin was the most transparent in the region where the refractive indexes of both the filler and the matrix agreed, and that a considerable reduction in translucency was caused when a difference in refractive index of only 0.02 occurred.

Fig. 2

Changes in translucency of hardened composite resin by differences in refractive index between filler and matrix

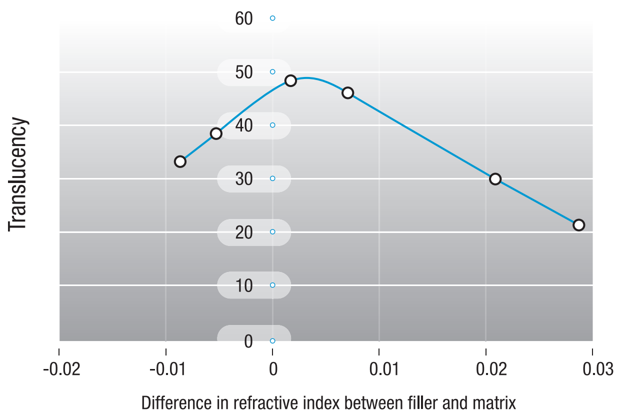


Fig. 3

Changes made in the translucency of hardened composite resin plates by changing the size of the nanofiller particles *(Terakawa et al., IADR, 2004).*

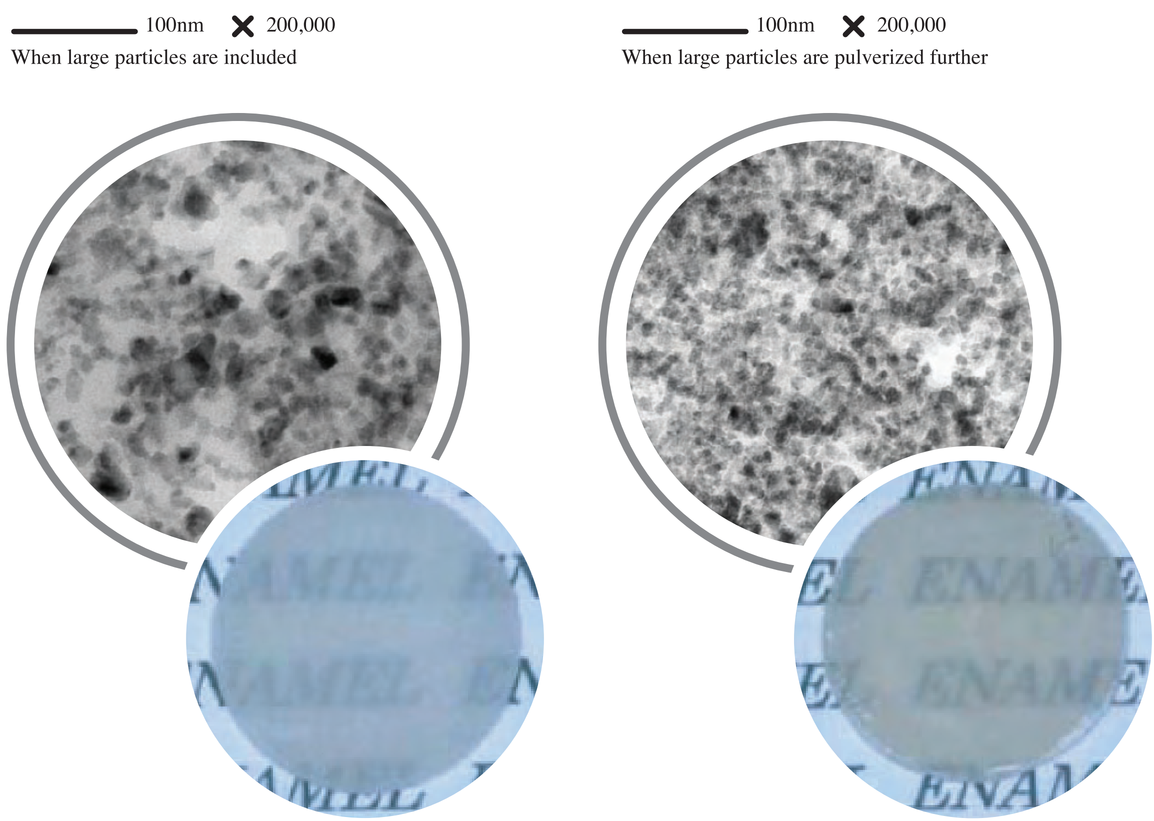


Fig. 3 shows changes made in the translucency of hardened composite resin plates by changing the size of the nano filler particles. The average size of the nano filler particles shown in the left TEM photo is about 20 nm. As you can see, the nano filler is made up of large particles that cause light scattering, thus lowering the translucency of the hardened composite resin. On the other hand, as

shown in the right photo, if the filler is composed of smaller particles, the hardened composite resin plates have improved translucency.

POLISHABILITY

Composite resin becomes more polishable as the particle size of the filler becomes smaller. It is difficult to avoid the occurrence of irregularities at the interface between the inorganic filler and the organic matrix during polishing, because they have different levels of hardness. Therefore, such irregularities that may occur should be small enough to have no effect on the light-scattering property of the composite resin. For this reason, also, the use of small filler particles is effective.
Earlier composite resins were filled with material having an average particle size of more than 10 µm but the average particle size has recently tended to be smaller. The general recently used average particle size ranges approx. 0.7 µm to 1 µm. The filler is usually manufactured using a pulverizer. The current lower limit of the particle size range seems to be approx. 0.4 µm.

Another means of manufacturing filler material is by build-up process that includes gas phase synthesis. Silica with an average particle size of approx. 40 nm has long been used in the manufacture of composite resin, but the average particle size has recently dropped to approx. 20 nm. The composition of the filler has also tended to be more diverse, going from a single oxide of silica to silica-zirconia composite oxides and others. Composite resin filler can also be synthesized using another build-up process, the sol-gel method. A silica-zirconia composite oxide is mainly used to manufacture monodispersed spherical filler. In addition, some researchers have tried to use fine inorganic oxide sol as the filler for dental composite resin (DE2947129, US4217264, and others).

Weak binding between the filler and matrix permits dislodging of the filler from the matrix during polishing, which causes irregularities on the surface of the hardened composite resin. Such irregularities will result in low gloss or permit later staining of the restoration. Therefore, mastering the surface treatment of the filler is essential technology for improving wetting and durability.

STRENGTH

To improve the strength of composite resin, it is important to increase the percentage of filler and enhance the binding between filler and matrix. The filler percentage can be increased by controlling filler particle distribution to ensure dense filling and by providing adequate surface treatment of the filler to ensure better wetting between the filler and matrix monomer and prevent increased viscosity.

Fig. 4 shows changes in the viscosity of paste by different types of surface treatment. The composite resin pastes were prepared by mixing the same percentage of alumina filler with an average particle size of 20 nm into the matrix monomer (Okada et al., IADR (1997)). When there is no surface treatment of the filler, the specimen incorporates air bubbles and becomes cloudy. You cannot call it a gel.
If surface treatment is performed using the same filler using γ-MPS, a substance often used in dentistry, the translucency increases to yield a clearer gel, but it is extremely viscous and there is a lot of air entrapped in the paste. By contrast, if the filler is subjected to the novel surface treatment method developed by Okada et al., the specimen retains a liquid form even though the same mixing ratio of filler to monomer is used. This indicates that the surface treatment of the filler is an important aspect of technology needed to increase the filler loading percentage.

Fig. 4
Changes in the viscosity of paste by different types of surface treatment
Left: no surface treatment Middle: γ-MPS treatment Right: novel surface treatment

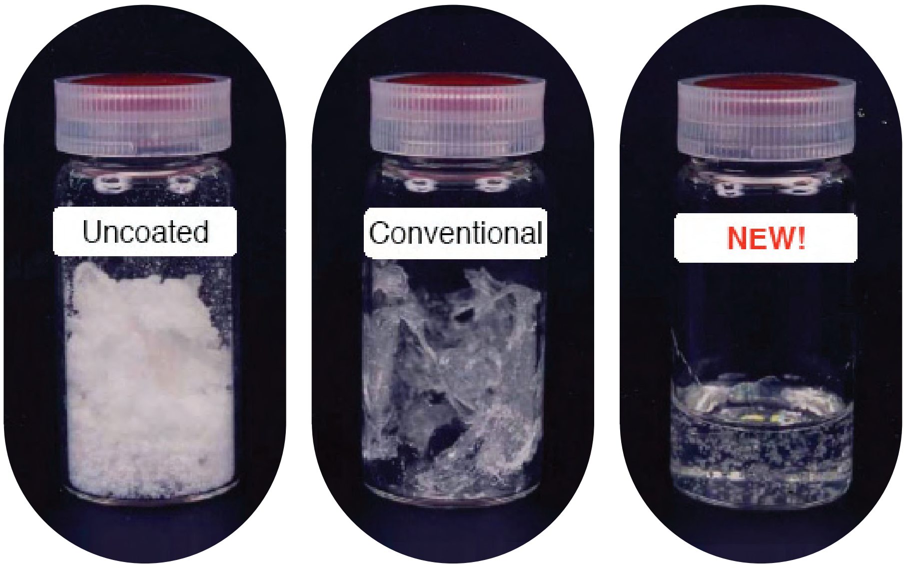
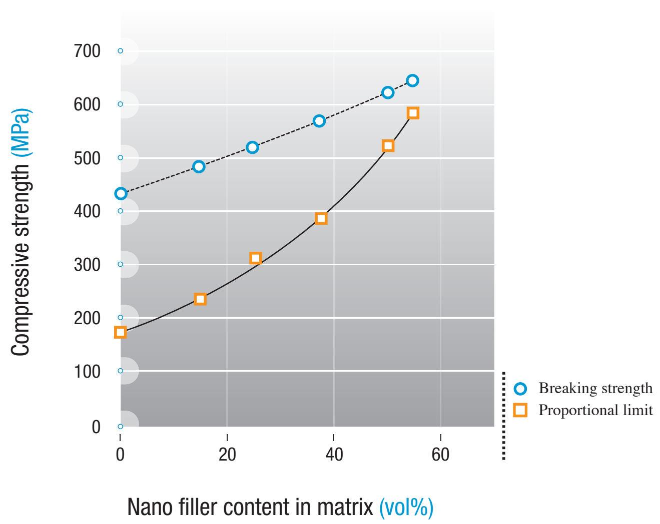
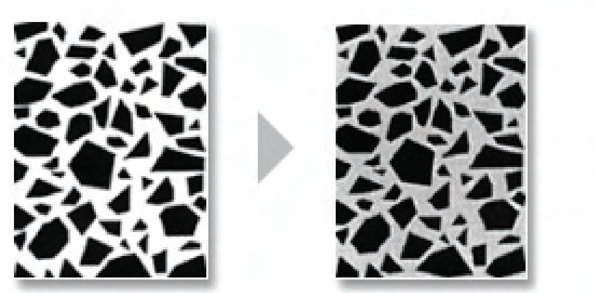


Fig. 5 shows the relationships between filler percentage, the compressive strength of composite resin, and the proportional limit of compression, with nanofiller added to composite resin loaded with particulate filler. As seen from the graph, both the compressive strength and the proportional limit of compression increase as the filler percentage increases (Okada et al., IADR (1997)).

Fig. 5
Changes in compressive strength and proportional limit of compression resulting when nanofiller is added.





RADIOPACITY

It has been reported that the radiopacity of composite resin can be increased by adding glass containing oxides such as barium, strontium or lanthanum (Bowen et al., J. Dent. Res (1969); US3826778; Muller, J. Dent. Res (1974) and others). Composite resins with various dental grades of radiopacity are commercially available.

A unique product is also commercially available featuring a high level of radiopacity, a composite resin that contains YbF_3 (DE3502594).

HANDLING CHARACTERISTICS OF THE PASTE

As mentioned above, controlling the handling characteristics of paste is fairly difficult. If the size of the filler particles is too small, the paste is prone to become sticky and rapidly become stiff when the quantity of extremely small-sized filler particles exceeds a certain limit. In addition, the use of fine particles provides more thixotropy to the paste, so that it becomes difficult to work with when being filled into the cavity. To prevent this from happening, larger particles are often used in combination with finer particles.

LOW POLYMERIZATION SHRINKAGE

The dimethacrylate monomer widely used in dentistry usually shrinks by about 7 percent after polymerization. This shrinkage can be reduced effectively by using more filler. General-purpose dental composite resins have an average filler content of 75 wt% to 85 wt%, while the flowable types have 60 wt%. The latter have a polymerization shrinkage rate of 2 to 5 percent. To reduce the polymerization shrinkage further, it is necessary to increase the filler content to more than 85 wt% while at the same time properly controlling the handling characteristics of the paste.

On the other hand, some researchers have proposed a new type of composite resin. In this type, a monomer with a ring configuration is designed to “open up” during polymerization to offset the usually occurring volume shrinkage; the volume increases due to the opening of the ring. Silorane, oxyrane, and spiro-orthocarbonate have been proposed as monomers with such a configuration. However, these monomers pose the problem that they cannot be used in combination with ordinary bonding agents, because they harden through cationic polymerization, unlike conventional dental materials which harden by radical polymerization (IADR 2006: Ernst et al., Johannes Gutenberg Univ.).

3. THE HISTORY OF KURARAY`S COMPOSITE RESINS

All of Kuraray's composite resin products are shown in Table 1 except for the composite resins used for core build-ups. Their development has been similar in some ways to competing products, but here we will explain the history of their development, focusing on the differences to other manufacturers' products.

In 1978, we launched **CLEARFIL™ BOND SYSTEM F**, our first dental composite resin system capable of bonding to tooth structure. From our **CLEARFIL™ F** to **F3** versions, the system used silica macrofiller as a main ingredient. In 1982, we released **CLEARFIL™ POSTERIOR**, a composite resin that can be used for restorations in posterior regions, based on a 4-functional urethane-based monomer. **CLEARFIL™ POSTERIOR** also contained macrofiller, but it provided radiopacity because it contained a radiopaque glass filler that had been developed for dental use. Since 1985, light-activation has become dominant in our composite resin system. Earlier, composite resins had been developed separately for anterior and posterior uses, but as the universal type became popular, in 1994 we launched **CLEARFIL™ AP-X**. Filled with 85 wt% inorganic filler, this product has a high mechanical strength and excellent stability in the oral cavity and is well accepted by the profession. Since its launch, it has been favorably regarded and used as a standard universal composite resin for more than 10 years.
Also, in view of the popularity of flowable composite resins in the market, we released **CLEARFIL™ FLOW FX** (in the Japanese market only), which features high radiopacity together with the ability to be conveniently placed in small cavities.
The following are the technologies unique to Kuraray's composite resin materials:

➔ *A multi-functional monomer that enhances the resin matrix:*
The resin matrix has been enhanced using our proprietary 4-functional urethane monomer, 6-functional monomer and others.

➔ *Our filler loading technology increases the percentage of filler incorporated:*
Compared with our competitors' products, the high percentage of filler in our composite resin has been attained by controlling the filler particle size distribution closely. The mechanical strength of the material has also been improved.

➔ *Filler surface treatment technology increases the percentage of filler in our composite resin and improves the durability of the hardened resin:*
The development of a new filler surface treatment technology has resulted in a high filler percentage and improves the compatibility of the filler with the matrix; this increases wear resistance and the level of other mechanical properties.

➔ *A new light-activated catalyst improves the setting properties of the composite.*
Compared with conventionally used camphorquinone, our new light-activated catalyst is not as yellow and has superior surface hardness. Its use will lead to the development of products with excellent color stability and durability.

Table 1

History of Kuraray's composite resin

	ANTERIOR	UNIVERSAL	POSTERIOR	FLOWABLE	C & B
1978	CLEARFIL™ F				
1981	CLEARFIL™ F II				
1982			CLEARFIL™ POSTERIOR		
1985		PHOTO CLEARFIL™ A			
1986	CLEARFIL™ F3 PHOTO CLEARFIL™ BRIGHT				
1987			CLEARFIL™ PHOTO POSTERIOR		
1989					CESEAD™
1991	CLEARFIL™ PHOTO ANTERIOR				
1992				CLEARFIL™ PHOTO SC	
1994		CLEARFIL™ AP-X			
1995					CESEAD™ II
1997					ESTENIA™
2000	CLEARFIL™ ST				
2001					Epricord™
2004				CLEARFIL™ FLOW FX	ESTENIA™ C&B
2007	CLEARFIL MAJESTY™ Esthetic		CLEARFIL MAJESTY™ Posterior	CLEARFIL MAJESTY™ Flow	

In the past, we worked to develop dental restorative materials with high mechanical properties and excellent durability. Recently, however, clinical needs have diversified and the demand for reliable restorations has increased. Keeping this in mind, we are now working on the development of products that feature low polymerization shrinkage in order to create a reliable adhesion interface, higher adhesiveness, antibacterial action, and other desirable qualities. In addition, we are also examining the possibility of developing products that change properties according to application and offer optical characteristics appropriate to the tooth structure, for more esthetic restorations.

4. THE CONCEPT BEHIND CLEARFIL MAJESTY™ SERIES

Combining improved esthetics and excellent physical properties, filling composite resins have come to be widely used in the clinical dental field. Filling composite resins for anterior teeth must have excellent esthetics and be easy to handle, while those for posterior teeth must be sufficiently strong and durable. This makes it difficult to achieve the same high levels of all the required properties in both types of composite. When developing a new composite resin, we divided our goals into two categories from the development stage, to satisfy the above requirements: a universal type that is focused on use for anterior teeth and a posterior type that features desirable physical properties, including durability, low polymerization shrinkage and a low thermal expansion coefficient, to ensure reliable restoration in large cavities. Whilst flowable composites are widely used, many dentists have expressed concern about their use. We improved the physical properties of the flowable type of composite resin to allow it to be used safely for the restoration in the posterior region.

5. FEATURES OF CLEARFIL MAJESTY™ SERIES

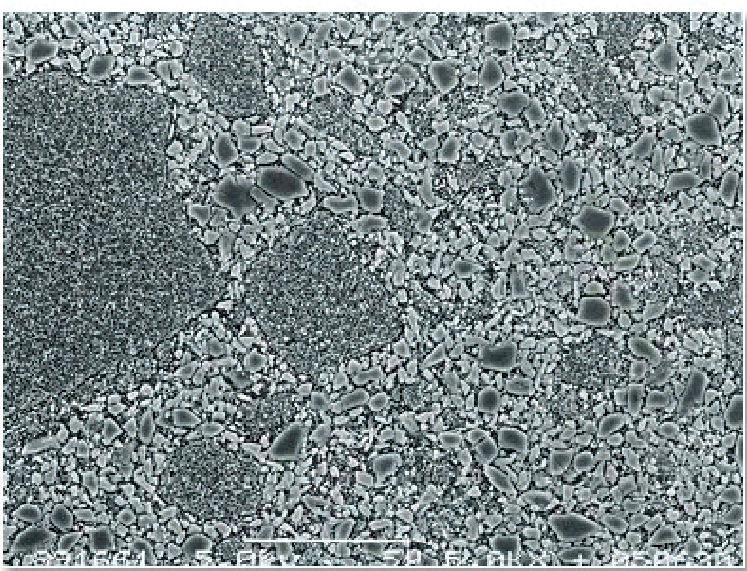
5.1 CLEARFIL MAJESTY™ Esthetic

Many currently available dental composite resins, that emphasize esthetic qualities offer a large number of shades and intend to reproduce the target tooth color through layered restoration. However, it took years of experience gained in the actual clinical setting for dentists to determine how much dentine paste should be used and where and how much enamel paste should be applied, to suit individual patients who had different dental states. In addition, since the use of fine fillers, such as nano-size filler, became popular, the dentists have encountered handling problems, like high viscosity and rapid changes in the consistency of the paste during use.

With a view to reducing such problems, we developed **CLEARFIL MAJESTY™ Esthetic** with the goals of: 1) mechanical properties worthy of a universal type of composite resin; 2) easy, simple color matching with a minimal number of shades; 3) a minimum change in color and transparency after polymerization so that shade matching can be accurately judged at the filling stage; 4) excellent polishability; 5) ease of paste handling, with little change in properties during use.

Fig. 6 shows an SEM picture of **CLEARFIL MAJESTY™ Esthetic**. **CLEARFIL MAJESTY™ Esthetic** is heavily filled with particulate filler of a submicron size, among which a larger organic-inorganic composite filler including nano filler is dispersed. In the picture, some particulate filler particles appear blackish. This is probably because of the difference in the reflection of the electron beam possibly due to steps taken in the preparation of the sample.

Fig. 6
The microstructure of **CLEARFIL MAJESTY™ Esthetic** (by courtesy of Dr. Yamada of Toranomon Hospital).



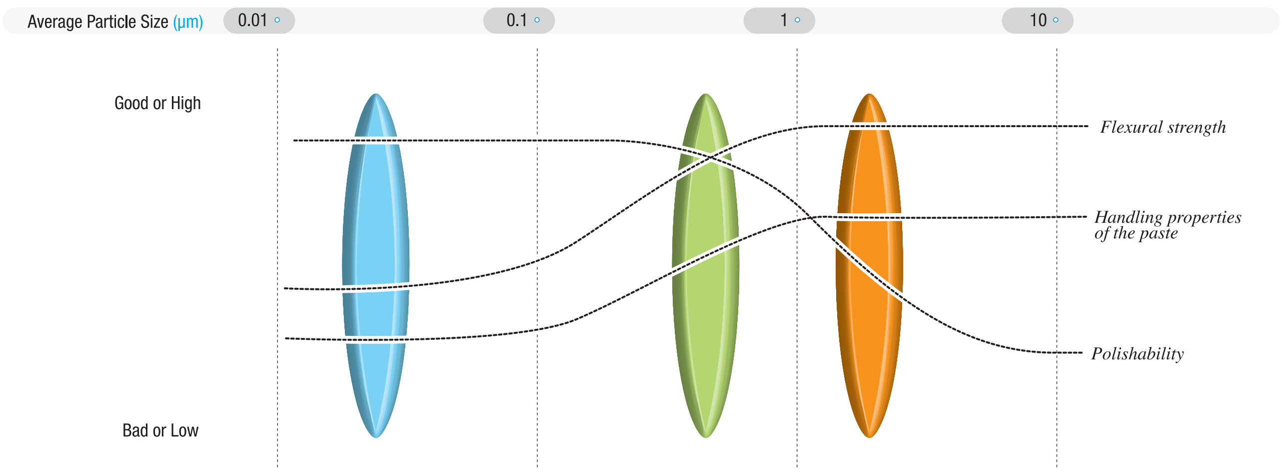
The technologies used to attain the desired characteristics are explained below:

1. FILLER COMPOSITION

Fig. 7 shows a schematic diagram of the relationships between filler particle size in composite resin and resultant characteristics, for the three factors of flexural strength, handling properties of the paste, and polishability.

The changes expressed in the sketch are not necessarily exact and should be regarded as indicating rough trends.

Fig. 7
The effects of average filler particle size on composite resin characteristics



CLEARFIL™ AP-X is filled mainly with filler in the orange range shown in this sketch. In this range, the mechanical and handling properties of the paste were good, but it had low polishability. On the other hand, when a large quantity of filler in the blue range was used, like **PHOTO CLEARFIL™ BRIGHT** or **CLEARFIL™ ST**, polishability was improved, but the mechanical properties decreased and the handling properties of the paste also dropped. The handling properties of the paste could be improved by combining organic-inorganic filler in the mix. But the mechanical properties were not improved when organic filler was used. The mechanical property level attained was only suitable for anterior use. The use of a great deal of particulate inorganic filler in the green range made it possible to improve all three factors to a high level simultaneously. However, if filler in this range was used, the paste had a tendency to become too viscous, stiff or sticky to handle. Thus we realized we needed some new ideas if we were to attain better handling properties. We examined the possibility of using a variety of substances, including organic-inorganic composite filler and nano-cluster, and found that using organic-inorganic filler was effective in terms of the balance of physical properties.

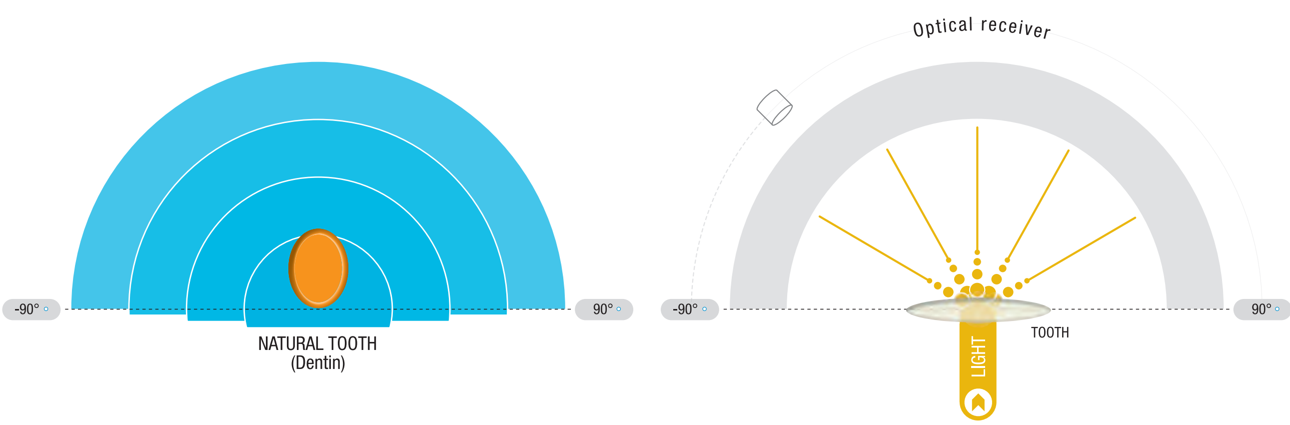
2) LIGHT DIFFUSION

Development in this field has often aimed at increasing the translucency of hardened resin to improve matching the color of the surrounding teeth. It was found from experience with past clinical cases that composite resins thus developed could not reproduce the intended shade under some circumstances. These circumstances include the type of cavity and tooth structure surrounding the filling, because the materials were strongly affected by the background in which they were installed. To be more specific, this arises in cases of Class III or IV cavities without any remaining tooth structure at the rear or in cases where the labial side of a canine is to be filled after the first premolar has been repaired with metal. Both cases involve a dark background or dark metal at a slight distance, whereas normally there is a light background in contact with the hardened composite resin.

This may make it easier to understand the influence of a background other than tooth structure, which manifests itself in a way that might be called a chameleon effect.

Filling restorations of natural teeth almost never begin with an even and consistent thickness of the cavity. In addition, the thickness of the restoration varies with the direction of observation of the dentist or others who look at the patient's teeth. Thus you can assume that you cannot evaluate color matching solely by using the results of transparency testing with specimens of a certain thickness.

Fig. 8
Results of studying the light diffusion qualities of composite resins (Source: Kuraray Medical Inc.)

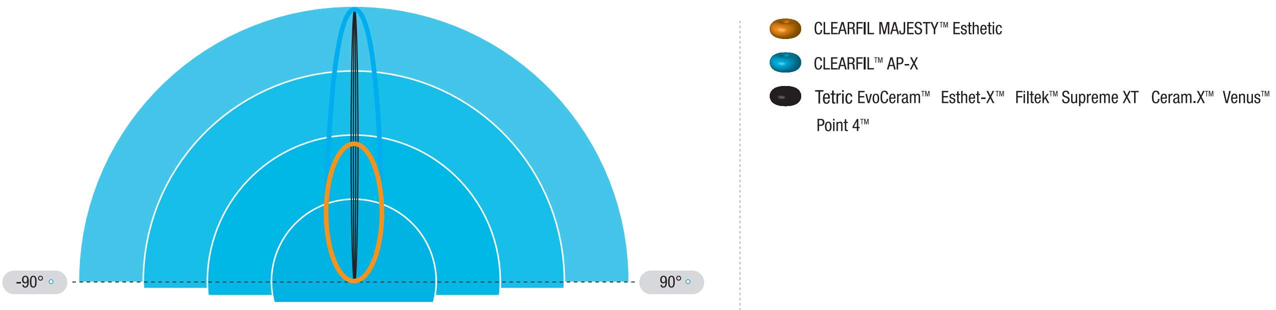


To clarify the reasons behind this phenomenon, Inokoshi divided natural tooth structure into enamel and dentin samples, and prepared thin sections of each separately, to determine the optical characteristics of the specimens. As a result, he found that there was a large difference in the light diffusion of enamel as compared to dentin, when they were illuminated by parallel rays which were closely narrowed. That is, the enamel allowed the light to pass through without being scattered much, while the dentin scattered the light in almost every direction. ***Fig. 8*** shows the results of this experiment. The right sketch shows the measurement method used.

Narrowly closed parallel rays were directed at a thin section. In the background, a goniophotometer was moved within a range of plus and minus 90 degrees to measure the intensity of the light emitted through the specimen. The results of the measurement are shown in the left sketch. *(You can see a strong peak projecting vertically from the specimen. This peak varied from specimen to specimen; it* *was concluded that the intensity of the light from some specimens was stronger because some sections were prepared too thin.)*

The large difference between the light diffusion of the enamel and dentin samples is thought to be for the following reasons: enamel consists of essentially a single phase of HAp and causes hardly any light to scatter, while dentin has a composite structure consisting of collagen fiber and HAp crystals with different refractive indexes, which causes much greater light scattering. On the basis of this finding, the light transmittance of some composite resins manufactured at that time was measured. It was found that they could be divided into two categories: those that transmit light well and those that greatly diffuse light. In addition, we found that the composite resins that could be used most successfully, without causing the above mentioned problems, were those with strong light diffusion characteristics.

Fig. 9
Results of studying the light diffusion qualities of composite resins (Source: Kuraray Medical Inc.)



It is not yet clear why composite resins with strong light diffusion qualities are clinically favorable, but one can assume the following: (1) It is required that a certain amount of light can enter the restoration and then reflect from it, to ensure that the restoration has the color and light-texture of natural tooth structure; (2) In a natural tooth, light penetrates the tooth and is scattered by the dentine in all directions. It reemerges through the surface of the tooth. Therefore, it is desirable for the restorative material itself to have similar light diffusion properties, in order to attain the same effect as natural tooth structure when the background of the restoration is empty space. Needless to say, composite resins with excellent light diffusion characteristics should also have conventional transparency. If they are not very transparent, a merely translucent restoration will result with low in value (brightness), similar to the situation when only opaque resin is used. It would be difficult to call this kind of restoration esthetic.

On the basis of the results of Inokoshi's experiment, various types of matrix monomer and filler were combined in a variety of ways. We finally achieved excellent light diffusion in a composite resin by loading it with a filler that measured more than a certain size and had more than a certain level of difference of refractive index against the matrix. However, we postponed the commercialization of the product because polishability is impaired by loading with large-sized filler particles. Strength is also reduced when an organic composite filler is used as the large particle-sized filler, making this product inadequate as a universal type. Also, it is difficult to ensure the translucency of the hardened resin if there is a large difference in refractive index between the matrix and the filler.

Since then, the filler pulverizing method has been improved, so it has become possible to produce submicron filler that can be heavily admixed while high transparency is retained. Heavy admixture of submicron-sized filler improves polishability while the full transparency of the composite resin is retained. Even some organic-inorganic composite filler can be used. In addition, it was confirmed that mixing organic-inorganic composite filler into the composite resin helps improve the paste's handling properties, which has been a problem of conventional products.

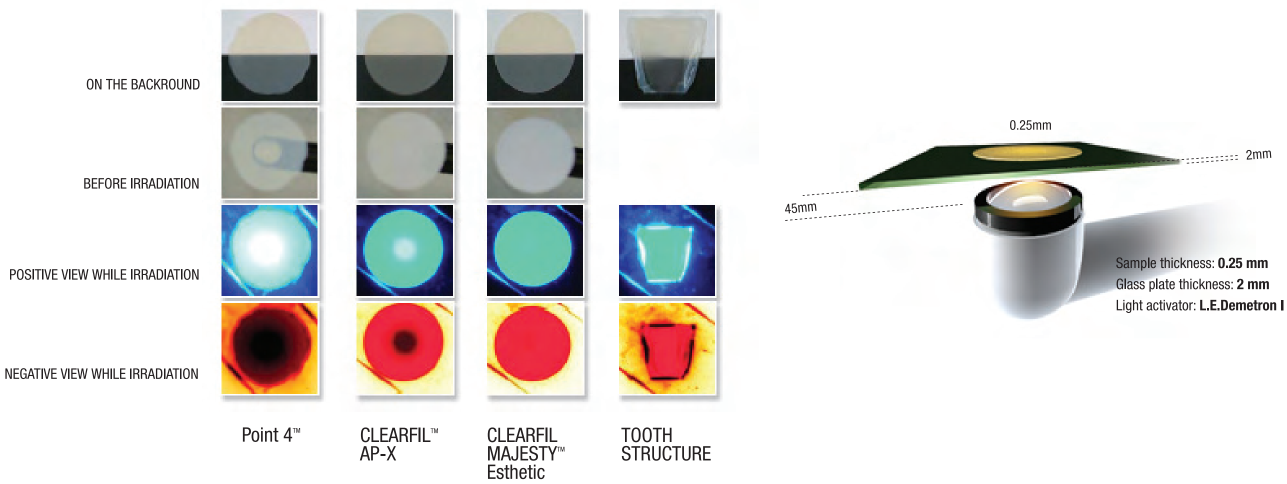
Fig. 10 shows differences in transparency and light diffusion between a high light-transmitting resin and **CLEARFIL MAJESTY™ Esthetic**, when the background is in contact with the samples and when the background is a few centimeters away from the samples. The differences in the light diffusion of the materials can be judged at least roughly, using this method.

Fig. 10
Usual comparison of transparency (samples in contact with background) and comparison based on light diffusion (samples not in contact with background).

Fig. 11 shows another view of light diffusion property. **CLEARFIL MAJESTY™ Esthetic**, **CLEARFIL™ AP-X**, **Point 4™** and a bovine tooth are compared with regard to their light diffusion characteristics. A composite resin disc (CR disc) or the tooth section is placed above the light guide tip face (exit window) of an L.E. Demetron I light activation unit. The distance between the light guide exit window and the disc was 4.5 cm. When the light curing unit was activated, the view of each disc was observed or recorded. Negative images as well as "positive views" are illustrated in this figure. When the CR disc was illuminated from 4.5 cm below, **CLEARFIL MAJESTY™ Esthetic** showed as a disc of uniform appearance. On the other hand, the light guide tip was clearly distinguishable through the CR disc for **Point 4™**. These images show the difference of light transmittance in the CR disc for these composite resins.

Fig. 11

CR discs appearance while being irradiated by the LED light activation unit positioned 45 mm below the disc. The outline of the light guide tip is easily observed for the light transmitting product but the CR disc shows a uniform appearance for **CLEARFIL MAJESTY™ Esthetic** (Source: Kuraray Medical Inc.).



We fabricated all-ceramic crowns with a Class III cavity that had no tooth structure on the lingual side. We filled one subject crown with **CLEARFIL MAJESTY™ Esthetic** and another with a different composite resin that transmits light with very little scattering, to compare the light transmission of the two composite resins. ***Fig. 12*** shows the results of the comparison.

One can see that the restoration appears darker when a composite resin with very little light scattering is used in comparison to when **CLEARFIL MAJESTY™ Esthetic** is used, because of the background effect.

As previously mentioned, dentine has different light diffusion properties than enamel. We prepared a composite resin with a similar quality of light diffusion to dentine as a trial. Using this new composite resin, we restored a tooth up to the enamel to study whether an esthetic restoration would be achieved. The results were good. On the basis of those results, we have adopted a mono-layering technique to be used as the basic procedure for esthetic filling restorations made with **CLEARFIL MAJESTY™ Esthetic**. We provide nine standard shades.

Fig. 12

Comparison of the appearance of **CLEARFIL MAJESTY™ Esthetic** and another composite resin that transmits light with very little scattering.

CAVITY

Restauration with regular esthetic composite (FSX) using 1 shade only. A dark shadow can be seen.

Restauration with **CLEARFIL MAJESTY™ Esthetic** with 1 shade only.

In some cases the floor and / or walls of a cavity is severely stained because amalgam was used for a previous restoration. In this case, the color of the cavity floor cannot be hidden completely using only conventional transparent resins. Then it becomes necessary to use an opaque material as an auxiliary measure.

The dentist might want transparency at the incisal edges or to use a laminated technique for restorations. Then he or she will need some shades that are quite transparent or that diffuse light only slightly. To meet such special needs, **CLEARFIL MAJESTY™ Esthetic** provides eight types of complementary shades to meet a variety of dentists' requests.

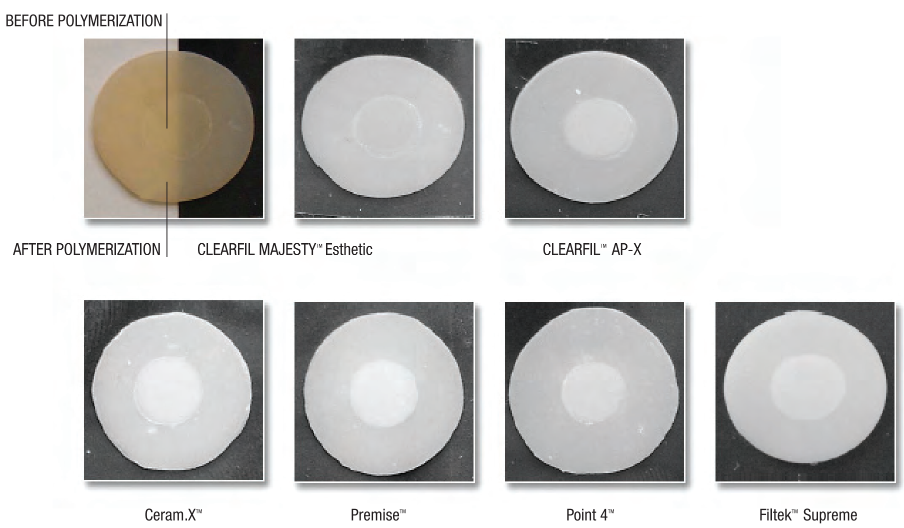
3) Reducing changes in transparency and color caused by polymerization

It is clinically important that the transparency or color of composite resins does not change significantly due to polymerization. Post-polymerization changes in transparency are usually caused by the fact that the refractive index of the matrix monomer tends to increase due to a rise in matrix monomer density during polymerization. Therefore, it seems plausible that changes in transparency might be suppressed by adjusting the refractive index of the filler so that it falls between that of the matrix monomer and that of hardened composite resin. This idea can be more easily understood by examining ***Fig. 2***. Actually, more precise control is required than described above, because multiple types of filler with different indexes are used, and they are loaded in different percentages, so they have different effects on the transparency of the composite resin. Among previous composite resins from Kuraray Medical Inc., **PHOTO CLEARFIL™ BRIGHT** only underwent a small amount of change due to polymerization. With the technology available at that time, we could not increase the transparency of the filler itself enough, so this product provided only a moderately improved level of transparency. Now, however, as mentioned above, we have succeeded in using pulverized fillers of submicron size. In addition, we have increased the percentage of a less viscous monomer (although it has an aromatic ring) in the matrix monomer formulation. The refractive index of the matrix as a whole has been increased so that changes in transparency due to polymerization can be suppressed and the hardened resin exhibits a high degree of transparency.

To study changes in transparency and color due to polymerization, we made discs from various composite resins. Each had a hole in the center. We cured them, and then put the same thickness of paste of the same composite resin into these holes. ***Fig. 13*** shows the hardened composite resin discs with the holes in the center filled with the unpolymerized paste of the same type. We selected from these samples the shade of each composite resin that minimized the effect of the coloring agent contained in the resin. You can see that for **CLEARFIL MAJESTY™ Esthetic** there is almost no difference in transparency and color caused by polymerization.

Fig. 13

Comparison of the transparency and color of composite resins before and after polymerization (Source: Kuraray Medical Inc.).



5. FEATURES OF CLEARFIL MAJESTY™ SERIES

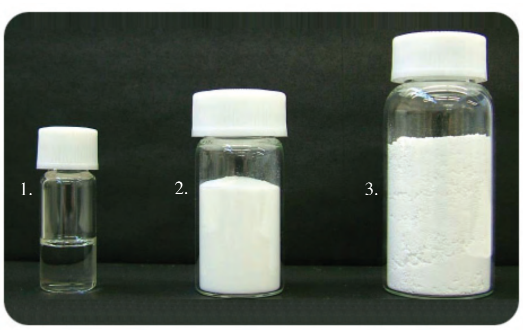
5.2 CLEARFIL MAJESTY™ Posterior

Composite resins have recently come into wide use for the direct filling restoration of posterior teeth. Many posterior composite resins have sufficiently good physical strength for use in posterior regions where strong biting forces are applied. However, cavities in posterior teeth are usually so large that if a composite resin with a high degree of shrinkage is used, the bonding agent must be able to cope with polymerization shrinkage and the resultant shrinkage stress. Therefore, concerns arise that secondary caries due to marginal leakage may occur if the bonding agent cannot deliver sufficient bonding strength. As stated above, polymerization shrinkage can be dealt with either by increasing the filler loading or by reducing the polymerization shrinkage of the monomer. If we will use the ring-opening polymerization system to suppress shrinkage, radical polymerization will not be allowed, and thus we lose the interchangeability of these products with our existing line of dental materials. In addition, mechanical strength and wear-resistance should not be compromised at the expense of reduced polymerization shrinkage. If they are, the durability against occlusal stress and other stresses due to temperature change in the oral cavity will be impaired and cast a shadow on prognosis. Giving full considerations to such problems, we employed the method of increasing the filler loading to reduce polymerization shrinkage and thermal expansion co-efficient in the development of **CLEARFIL MAJESTY™ Posterior**. By using this method we were able to develop a reliable posterior restorative composite resin.

As shown in ***Fig. 4*** and ***5***, we improved the filler treatment even more by using the strongly-hydrophobic surface treatment material developed by Okada et al. to optimize the filler particle size distribution, and increased the filler loading substantially to enhance the matrix properties. The innovative filler surface treatment technology **»Nano Dispersion Technology«** allowed us to increase the filler percentage to 92 wt% (82 vol%) so that a mechanical strength (flexural strength 177 MPa and compressive strength 504 MPa) was attained that was extremely high, in fact the highest ever. Volumetric polymerization shrinkage was reduced to as low as 1.5 % by increasing the filler loading to this high level. For reference, the shrinkage of **CLEARFIL™ AP-X** had been the lowest in the past, at 1.9 %. The thermal expansion coefficient of **CLEARFIL MAJESTY™ Posterior** (15.0 10^{-6}/ºC) approximates to that of tooth structures. Using **CLEARFIL MAJESTY™ Posterior** in combination with **CLEARFIL™ SE BOND, CLEARFIL™ S³BOND** or **CLEARFIL™ PROTECT BOND** will improve reliability and reduce stresses that might occur in the oral cavity during and after restoration, thus leading to a good prognosis.

Fig. 14

Loading matrix monomer and filler percentages in **CLEARFIL MAJESTY™ Posterior.**

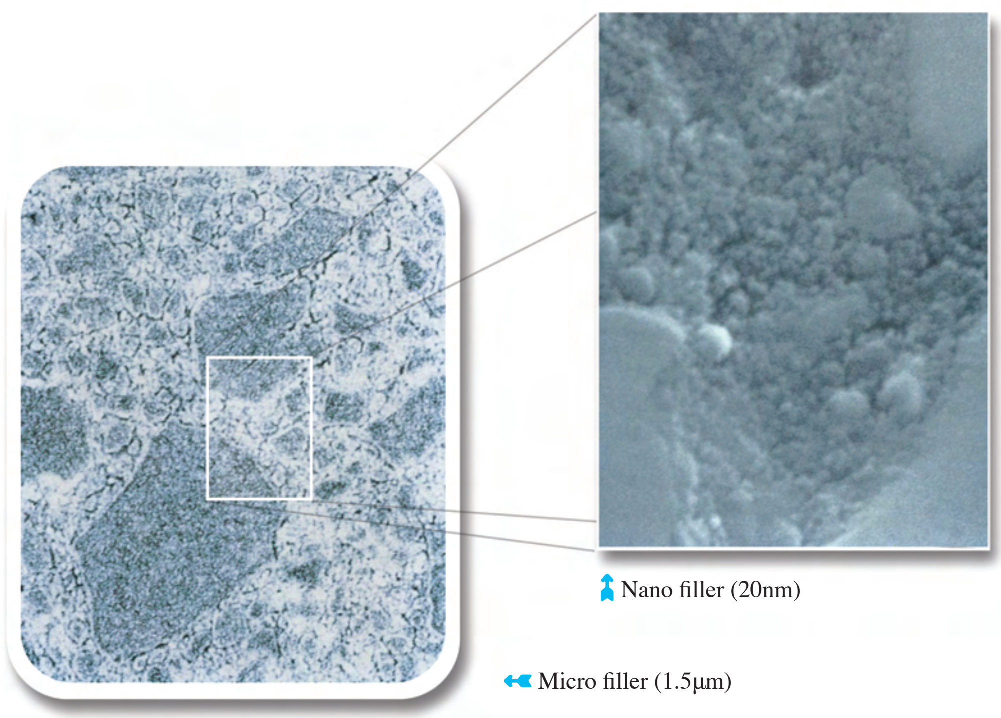


1. Matrix monomer
2. Micro filler
3. Nano filler

After investigating in detail the types of fillers to be used, we adopted alumina nano filler because it enhances the matrix more efficiently than the conventional silica nano filler. We used Glass Ceramics as the pulverized filler; it contains fine metallic oxide ceramic particles in glass. This allowes the filler to harmonize with the resin matrix with enhanced optical characteristics, contributing to the high wear-resistance of the hardened surface of **CLEARFIL MAJESTY™ Posterior**. ***Fig. 14*** shows the percentages of monomer, pulverized glass filler and alumina nano-filler in **CLEARFIL MAJESTY™ Posterior**. In ***Fig. 15*** the result of observations of the microstructure of the product are shown. You can see the nano-filler, which is present in large amounts in the matrix between the particles of Glass Ceramics. On the other hand, we also changed the matrix monomer from Bis-GMA/TEGDMA to a strongly hydrophobic one to reduce the water sorption of the hardened composite. In **CLEARFIL MAJESTY™ Posterior** water sorption was reduced from 16.2 µg/mm^3 (**CLEARFIL™ AP-X**) to 9.7 µg/mm^3. It is to be expected that the durability of restorations will be prolonged by reducing this deterioration factor of restorations in the oral cavity.

Fig. 15

Microstructure of **CLEARFIL MAJESTY™ Posterior**



5. FEATURES OF CLEARFIL MAJESTY™ SERIES

5.3 CLEARFIL MAJESTY™ Flow

Recently the use of flowable composite resin is increasing because it can be directly inserted through a cannula, to line with ease the bottoms of cavities with complicated shapes. More recently, some dentists are using flowable composite resin alone to restore minor cavities. However, concern about strength cannot be eliminated because the filler loading is only around 60 wt%, and a sufficiently strong flowable composite resin is wanted. In addition, we saw there was room for improvement in the containers of flowable composite resins, because the syringes and cannulas sometimes posed the problems of runny paste or the entrapment of air in a restoration.

We optimized the innovative filler surface treatment »**Nano Dispersion Technology**« used for the development of this type of posterior composite resin and adjusted the filler particle size distribution properly to produce a flowable resin. This improved the compatibility between the filler and matrix resin monomer and succeeded in achieving good resin fluidity even though the filler loading percentage was increased to 81 wt% (62 vol%). This figure for **CLEARFIL MAJESTY™ Flow** compares with that of **CLEARFIL™ AP-X**, which has a reputation for strong mechanical properties and durability. Thus **CLEARFIL MAJESTY™ Flow** is unique among flowable composite resins. However, to provide flowability desirable in such a composite, the filler consists of a combination of barium glass and silica nano filler. The high filler loading of **CLEARFIL MAJESTY™ Flow** provides desirable physical properties, including linear polymerization shrinkage of 1.9 % and flexural strength at 145 MPa, making this product clinically reliable as a flowable composite resin.

The paste hardly runs even when placed on a vertical plane, yet it is soft enough to be easily spread over the bottom of the cavity, so a variety of cavity types can be filled with a single type of paste. *Fig. 16* shows a comparison of fluidity and consistency of pastes of various flowable composite resins, including **CLEARFIL MAJESTY™ Flow** and the high-flow and low-flow types currently available.

Fig. 16

Comparison of the fluidity and consistency of **CLEARFIL MAJESTY™ Flow** and other flowable composite resins

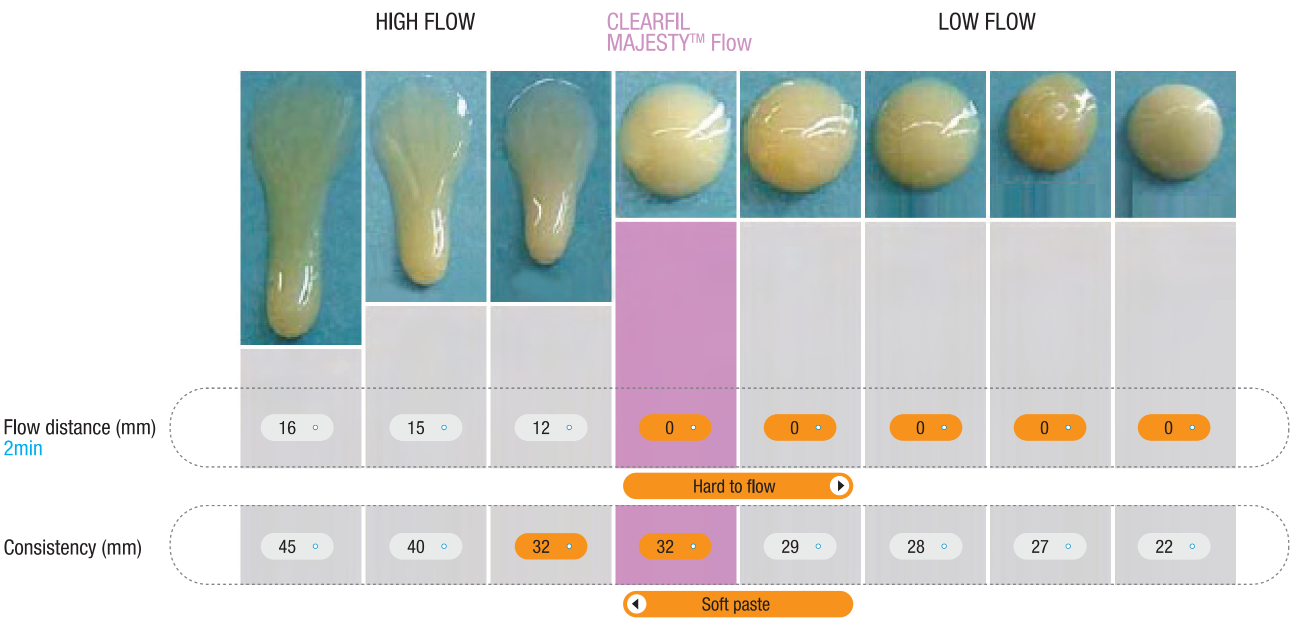


Fig. 17 shows **CLEARFIL MAJESTY™ Flow** filled into a Class V cavity. As you can see, **CLEARFIL MAJESTY™ Flow** can be easily filled into such a cavity without running. *Fig. 18* shows a cross-sectional view of **CLEARFIL MAJESTY™ Flow** used for lining a cavity in an extracted human tooth. Our new flowable composite adheres tightly to the bottom of the cavity because it is able to "wet out" or adapt well to the bonding layer. Some conventional flowable resins do not "wet out" the cavity or bonding material layer, causing concern to the dentist in the clinical setting.

Fig. 17 & Fig. 18

Fig. 17 Filling of a Class V cavity. Fig. 18 Bottom of cavity lined with **CLEARFIL MAJESTY™ Flow**

Fig. 17

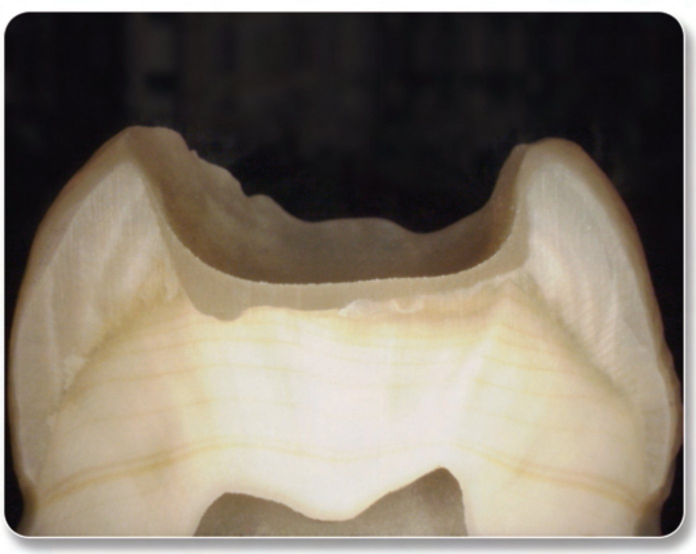


Fig. 18

Most flowable composite resin products are designed so that the necessary amount of paste can be dispensed by pushing on the piston of the syringe. However, with many conventional containers, excess paste flows out even after there is no more pressure on the piston. Many dentists have mentioned that this point needs to be improved so that the correct amount of paste can be dispensed, and so allow the correct contour to be given to the restoration. While developing **CLEARFIL MAJESTY™ Flow**, we gave due consideration to the design of the containers, so the paste stops flowing out immediately when pressure is taken off the piston after the desired amount of paste has been dispensed (patent pending).

The entrapment of air bubbles in the paste has been substantially reduced, as compared with conventional flowable composite products, by using our new surface treatment technology to improve the "wetting action" between the filler and matrix monomer. In addition, we reduced the possibility of incorporating air into the paste during replacement of the cannula. Providing restorative treatment has become smooth and easy because entrapment of air, one of the main problems causing a defective restoration, has been reduced.

The filler content of **CLEARFIL MAJESTY™ Flow** has been increased by using our new surface treatment technology, so that much better mechanical properties have been achieved. It is thus expected that long-term prognoses will be improved. In addition, we gave full considerations to the handling characteristics, including the paste properties and containers. We took the suggestions of many dentists into account, and made **CLEARFIL MAJESTY™ Flow** an easy to use, less problematic flowable composite resin.

6. PRODUCT DESCRIPTION

6.1 CLEARFIL MAJESTY™ Esthetic

Product description

CLEARFIL MAJESTY™ Esthetic is a light-curing, radiopaque restorative composite resin (filler contents: 78 wt%, 66 vol%) that contains proprietary nano-filled composite filler (new organic filler including nano filler) and a high refractive matrix (including radiopaque submicron filler: average 0.7 µm). With its highly developed new nano-filled composite filler, **CLEARFIL MAJESTY™ Esthetic** exhibits light diffusion properties similar to natural tooth structure. We developed a new name to more precisely describe this remarkable shade matching feature. The new name is »Optical Tooth Mimetic«. The »Optical Tooth Mimetic« feature enables the dentist to avoid having to use complex multi-layering techniques (in other words: 1-shade restoration technique). **CLEARFIL MAJESTY™ Esthetic** provides an outstanding and versatile shade matching for almost any restorative situation. Also, the high refractive matrix provides another essential benefit, a very minor transparency shift after light curing. **CLEARFIL MAJESTY™ Esthetic** also has a shapeable consistency with high polishability, low polymerization shrinkage (1.9 vol%), and is very easy to handle.

Composition

Silanated barium glass filler (average: 0.7 µm) · Pre-polymerized organic filler including nano filler · Bis-phenol A diglycidylmethacrylate (Bis-GMA) · Hydrophobic aromatic dimethacrylate · dl-Camphorquinone · Initiators · Accelerators · Pigments
Others

Shades

Standard shades (9 shades):
A1, A2, A3, A3.5, A4, B2, B3, C3, HO (Hollywood Opaque)

Complementary shades (8 shades):
Transparent shades: T (Transparent) , AM (Amber)
Enamel shades: E (Enamel), XL (Extra Light), OC (Occlusal)
Opaque shades: OA2, OA3, OA4

The standard shades are used for the 1-color shade restoration technique in most clinical cases. Therefore the inconvenient multi-layer technique can be neglected to achieve high esthetic results. 1-color shade is selected from the 9 standard shades due to the superior characteristics of **CLEARFIL MAJESTY™ Esthetic**: the light diffusion characteristics are similar to dentine and the high transparency is suitable for marginal adaptation to enamel.

The complementary shades are composed of 2 transparent shades (T and AM), 3 enamel shades (E, XL and OC) and 3 opaque shades (OA2, OA3 and OA4) for special cases. The complementary shades are used for multi-layering technique in special cases, e.g. in the incisal area, cervical caries or root erosion, for discolored teeth, for only enamel restorations, etc..

6. PRODUCT DESCRIPTION

6.2 CLEARFIL MAJESTY™ Posterior

Product description

CLEARFIL MAJESTY™ Posterior is a light-curing, nano-superfilled, radiopaque restorative composite resin composed of nano and micro inorganic filler treated with a proprietary new surface coating technology »Nano Dispersion Technology«. The »Nano Dispersion Technology« permits a larger quantity of nano filler to be dispersed in the resin matrix, which consists of monomer and micro filler. The resulting resin matrix is reinforced with a filler load of 92 wt% (82 vol%). **CLEARFIL MAJESTY™ Posterior** has an improved high surface hardness close to that of human enamel (high wear resistance, but harmless against an antagonist tooth), high mechanical strength (compressive strength: 504 MPa, flexural strength: 177 MPa), high durability, high depth of cure, extremely low polymerization shrinkage (1.5 vol%) and very low thermal expansion coefficient (15.0 10^{-6}/ºC) similar to tooth tissue. These features assure a reliable posterior restoration with better marginal adaptation and a restoration that will last. In spite of the extremely high filler load, **CLEARFIL MAJESTY™ Posterior** also has a very shapable consistency and the high refractive matrix also provides another essential benefit, minimal transparency shift after light curing.

Composition

Silanated glass ceramic filler (average: 1.5 µm) · Surface treated alumina micro filler (average: 20 nm) · Bis-phenol A diglycidylmethacrylate (Bis-GMA) · Hydrophobic aromatic dimethacrylate · Triethyleneglycol dimethacrylate (TEGDMA) · dl-Camphorquinone · Accelerators · Pigments · Others

Shades

6 shades:

A2, A3, A3.5, B2, XL (Extra Light), OA3

6. PRODUCT DESCRIPTION

6.3 CLEARFIL MAJESTY™ Flow

Product description

CLEARFIL MAJESTY™ Flow is a flowable, superfilled, light-curing, radiopaque restorative composite resin with the filler particles treated with a proprietary new surface coating technology »Nano Dispersion Technology«. The resulting resin matrix is reinforced with an extraordinarily high filler load of 81 wt% (62 vol%), similar to many universal composite resins. In addition to the high filler load, **CLEARFIL MAJESTY™ Flow** has a low viscosity for good handling and easy placement. **CLEARFIL MAJESTY™ Flow** exhibits high mechanical properties (compressive strength: 329 MPa, flexural strength: 145 MPa) high wear resistance, high radiopacity (290 %Al) and very low polymerization shrinkage. These features make it a very versatile product with multiple uses (e.g. Class I, II). **CLEARFIL MAJESTY™ Flow** has an excellent consistency (appropriate flow, not runny, not sticky). Equally significant is the new **CLEARFIL MAJESTY™ Flow** dispenser, a new syringe that provides bubble free and controllable dispensing as well as exceptionally easy handling.

Composition

Silanated barium glass filler (average: 3 µm) · Silanated colloidal silica (average: 20 nm) · Hydrophobic aromatic dimethacrylate Triethyleneglycol dimethacrylate (TEGDMA) · dl-Camphorquinone · Accelerators · Pigments · Others

Shades

9 shades:
A1, A2, A3, A3.5, A4, B2, C3, Cv (Cervical), OA3

7. INDICATIONS

7.1 CLEARFIL MAJESTY™ Esthetic

- Direct restorations for anterior and posterior teeth (Class I – V cavities)
- Direct veneers
- Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
- Intraoral repairs of fractured crowns / bridges

7.2 CLEARFIL MAJESTY™ Posterior

- Direct restorations for anterior and posterior teeth (Class I – V cavities)
- Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
- Intraoral repairs of fractured crowns / bridges

7.3 CLEARFIL MAJESTY™ Flow

- Direct restorations for anterior and posterior teeth (Class I - III, V cavities, cervical caries, root erosion)
- Cavity base / liner
- Intraoral repairs of fractured crowns / bridges / composite resin

8. PHYSICOCHEMICAL INVESTIGATION

8.1 CLEARFIL MAJESTY™ Esthetic

Technical Data

CLEARFIL MAJESTY™ Esthetic

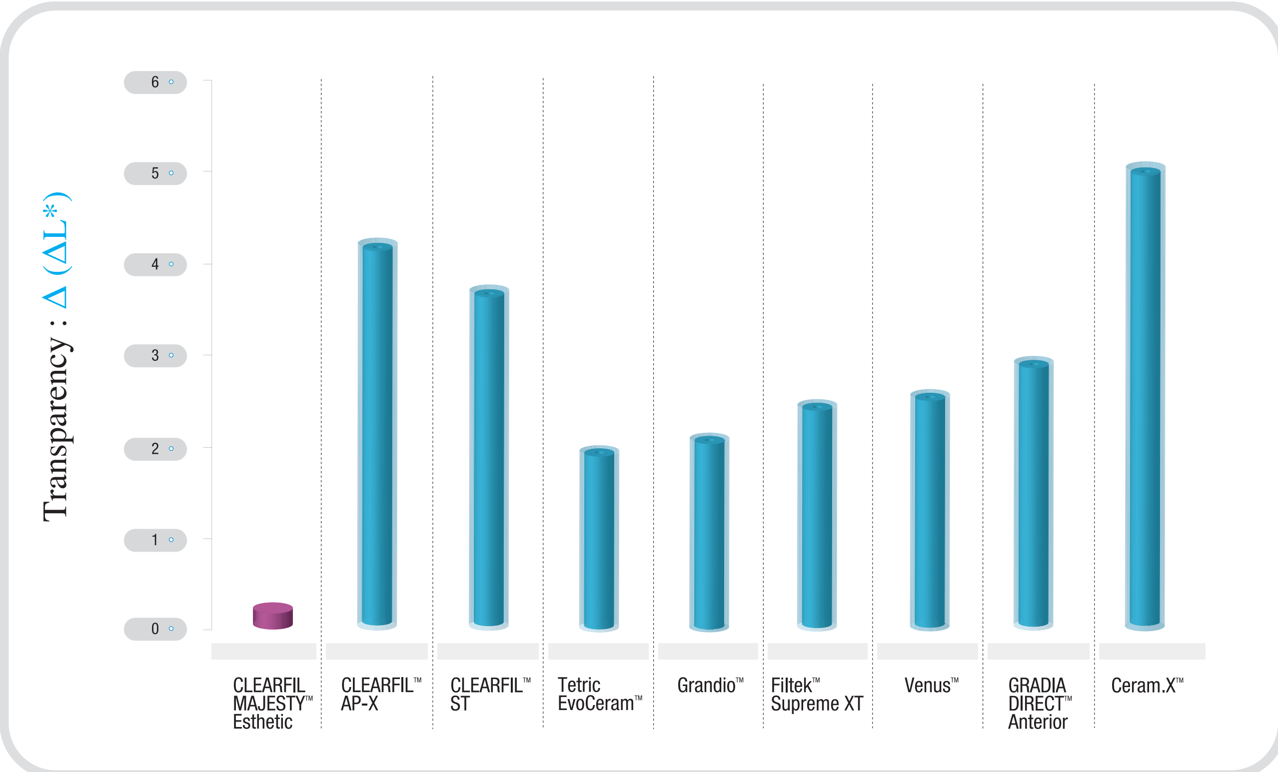
FILLER LOAD	*78 wt% (66 vol%)*
FILLER LOAD OF TRANSPARENT SHADES: T, AM	*77 wt% (61 vol%)*
COMPRESSIVE STRENGTH	*356 MPa*
FLEXURAL STRENGTH (ISO4049 : 2000)	*118 MPa*
MODULES OF ELASTICITY	*10.0 GPa*
VICKERS HARDNESS	*60 Hv*
WATER SORPTION (ISO4049 : 2000)	*25.3 µg/mm^3*
WATER SOLUBILITY (ISO4049 : 2000)	*< 1.5 µg/mm^3*
RADIOPACITY (ISO4049 : 2000)	*110 %Al*
RADIOPACITY OF TRANSPARENT SHADES: T, AM (ISO4049 : 2000)	*180 %Al*
VOLUMETRIC SHRINKAGE (ARCHIMEDES METHOD)	*1.9 vol%*
WEAR RESISTANCE (MODIFIED LEINFELDER METHOD)	*1.35 mm^3*

8.1.1 TRANSPARENCY CHANGE: BEFORE AND AFTER POLYMERIZATION

Transparency change of a composite before and after polymerization is one of the important barometers in evaluation of color matching for anterior restorations.
The transparency is evaluated based on the value of *'ΔL*(W/B)' (= L*(W)-L*(B))* of the polymerized disk with 1 mm thickness using spectrophotometer "CM-3610d" (Konica Minolta) under standardized light D65/2. *'L*(W)'* describes the value of lightness on a white background, and *'L*(B)'* on a black background. High value of *ΔL*(W/B)* means high transparency. Transparency change (before and after polymerization): *Δ(ΔL*)* show *ΔLa** (after polymerization) and *ΔLb** (before polymerization). *Δ(ΔL*) =ΔLa* -ΔLb**. The results clearly demonstrate that the shift in transparency of **CLEARFIL MAJESTY™ Esthetic** (shade: A3) is the lowest among the tested materials *(Fig. 19)*.

Fig. 19

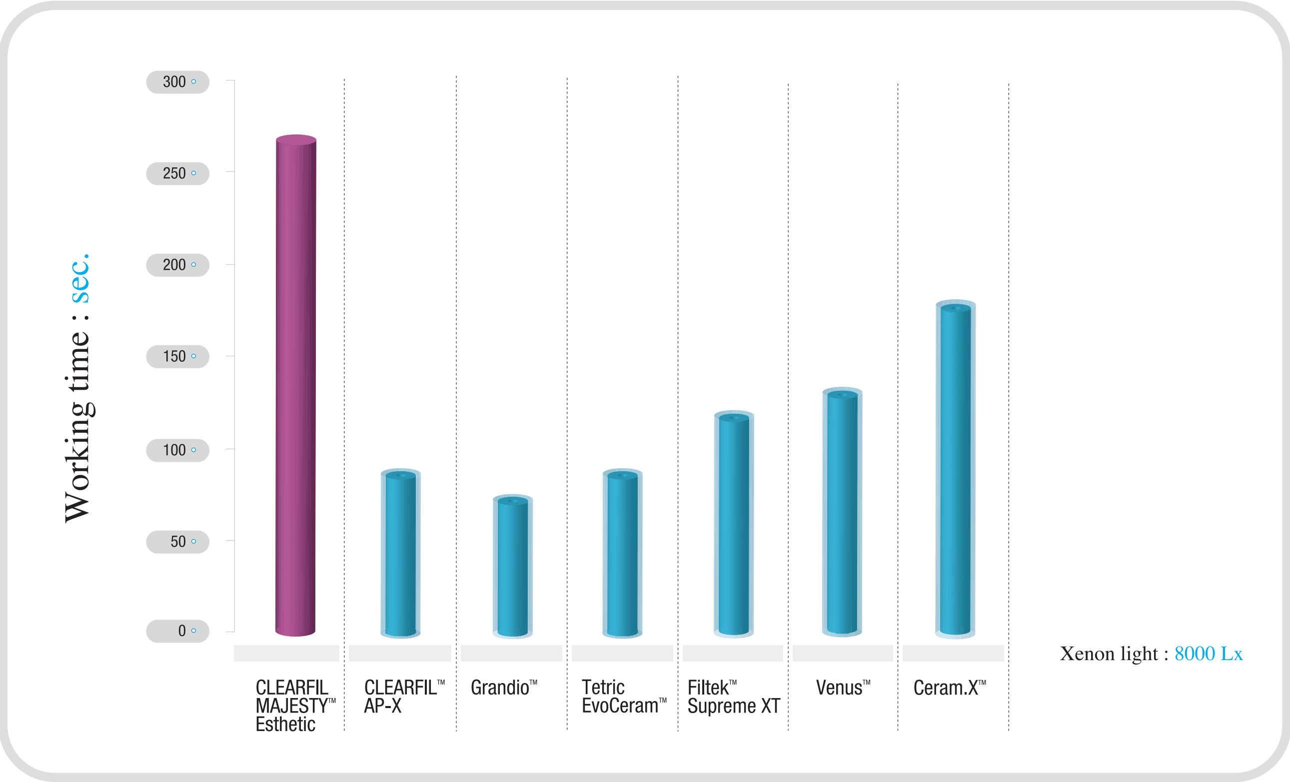
Transparency change: before and after polymerization (Source: Kuraray Medical Inc., Japan)



8.1.2 WORKING TIME: SENSITIVITY TO AMBIENT LIGHT

CLEARFIL MAJESTY™ Esthetic makes it possible to produce an esthetic restoration easily using only 1 color shade selected from the standard shades in most cases. Moreover, the complementary shades are indicated for demanding situations where there are unusually high esthetic demands. All shades have a low sensitivity to ambient light, and dentists can escape the stress caused by concerns about working time. The working time in ambient light (8,000lx) was measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Esthetic** showed the lowest sensitivity to ambient light of all the tested materials.

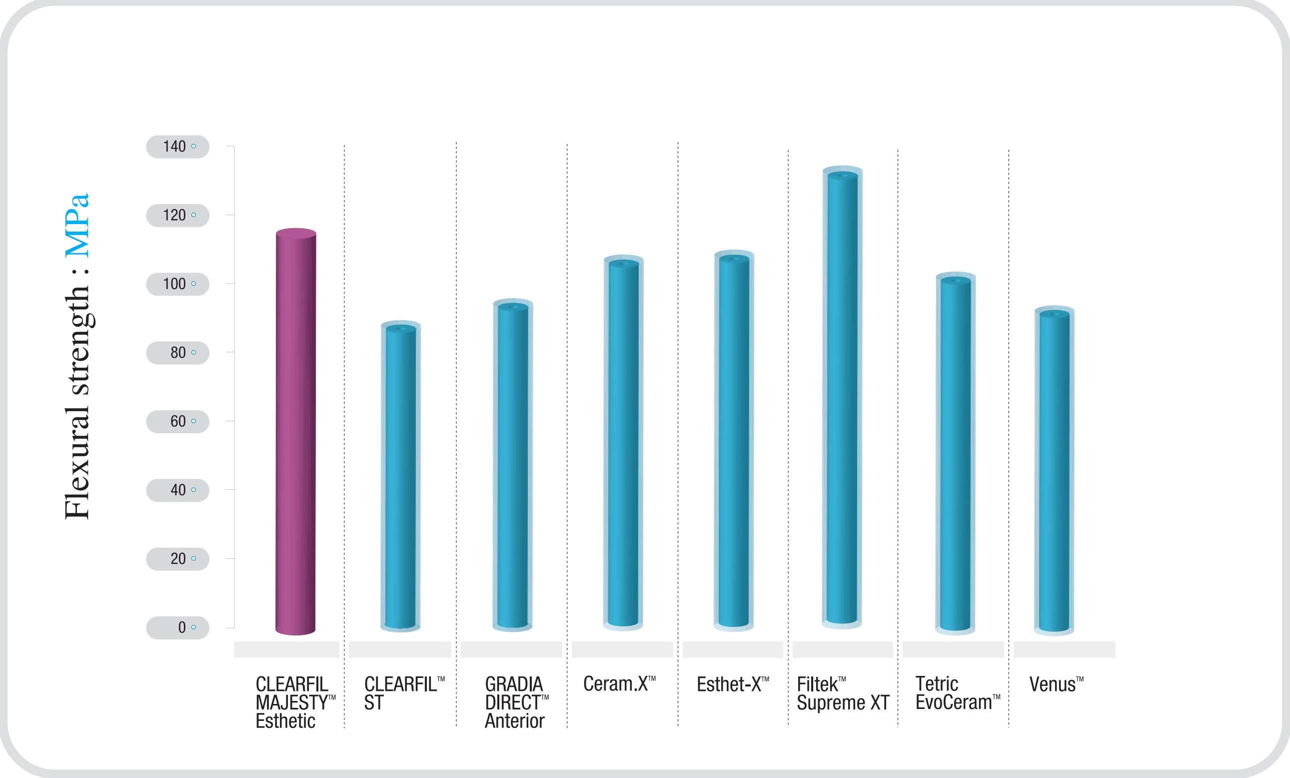
Fig. 20
Working time: sensitivity to ambient light (Source: Kuraray Medical Inc., Japan)



8.1.3 FLEXURAL STRENGTH

CLEARFIL MAJESTY™ Esthetic can be used for not only anterior restorations but also posterior restorations. The universal composite (for anterior and posterior restorations) requires superior mechanical strength. The flexural strength of a composite was measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Esthetic** showed higher flexural strength than **CLEARFIL™ ST** and was comparable to conventional hybrid composites.

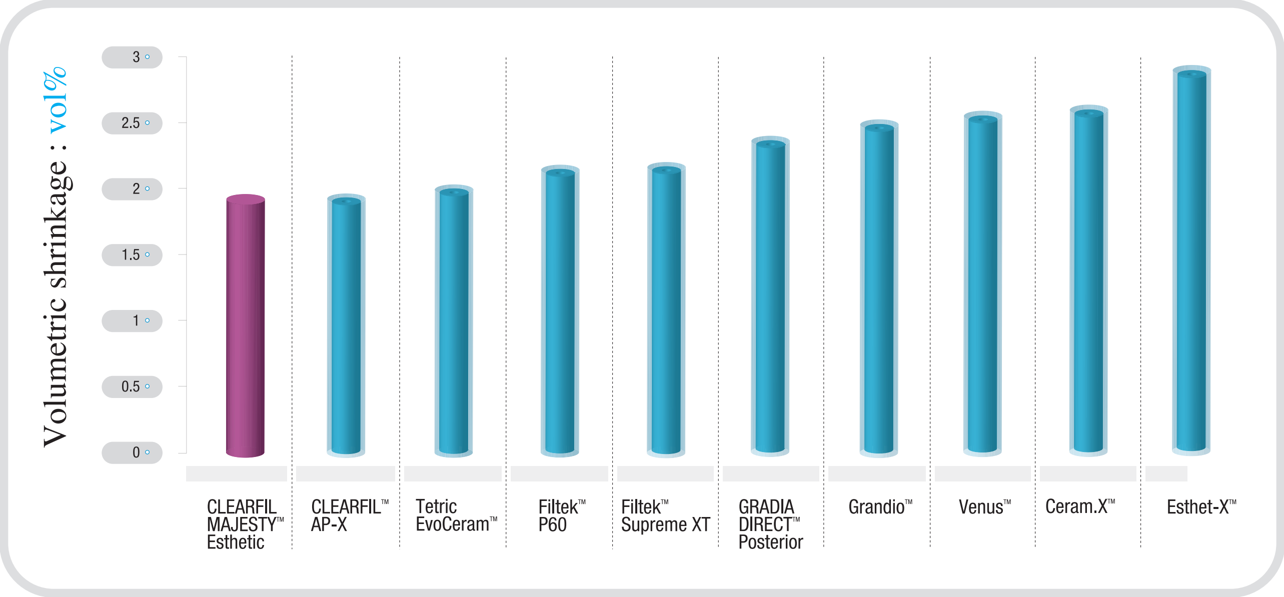
Fig. 21
Flexural strength (Source: Kuraray Medical Inc., Japan)



8.1.4 VOLUMETRIC POLYMERIZATION SHRINKAGE

Composite resin which contains methacrylate monomers generates shrinkage by polymerization. To reduce the monomer content of the composition is one of the most important measures. Moreover, the shrinkage stress at the adhesion interface might be reduced by the optimum selection of adhesive, light curing unit, filling method (increments), etc. Polymerization shrinkage was measured by computing the specific gravity change of the sample from before and after polymerization. For the measurement of specific gravity, an electronic hydrometer (A&D Ltd., AD-1653) that adopted the Archimedean method was used, and hexane was used as a medium in the measurement [ref: Y.Hatsuoka, K. Yamamoto, M. Inoue, Japan. J. Conserv. Dent. 45(6), 1060~1066, 2002]. **CLEARFIL MAJESTY™ Esthetic** showed lower volumetric polymerization shrinkage than all the other tested hybrid universal composites.

Fig. 22
Volumetric polymerization shrinkage (Source: Kuraray Medical Inc., Japan)



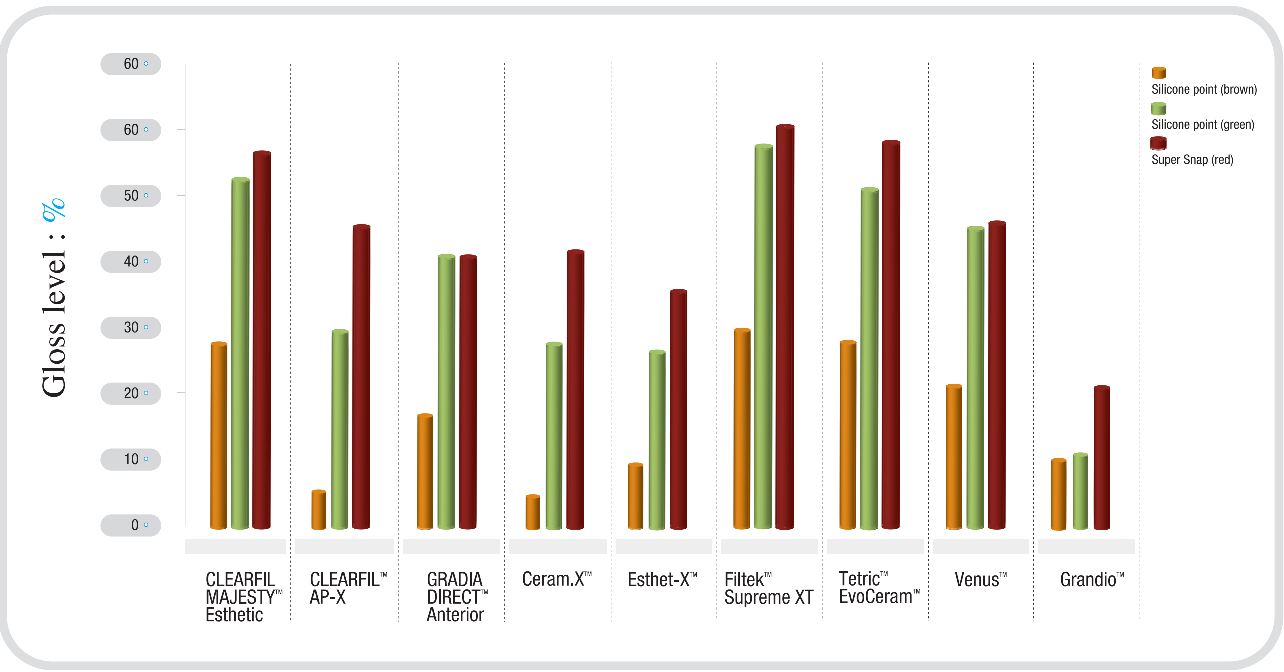
8.1.5 POLISHABILITY

High polishability is one of the most significant characteristics especially for anterior composites. The polishing method is also very important for dentists in their daily restorative work. High polishability should be achieved easily under the clinical condition. The cured composites were polished with Si-C papers up to #1500-grit. After that the specimens were divided into 3 groups.

1) Silicon Point brown (Shofu): wet, low speed (8,500rpm), 30 sec.
2) Silicon Point green (Shofu): wet, low speed (8,500rpm), 30 sec.
3) Super Snap red (Shofu): dry, low speed (8,500rpm), 30 sec.

The gloss level of each polished composite surface was measured with the glossmeter *[VGS-∑80; Nippon Denshoku]*, (incident angle: 60°, reflection angle: 60°). **CLEARFIL MAJESTY™ Esthetic** showed higher polishability than **CLEARFIL™ AP-X** and was comparable to hybrid composites which have good polishability.

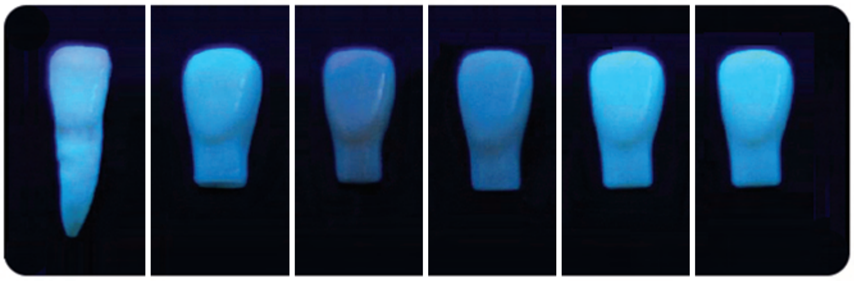
Fig. 23
Polishability (Source: Kuraray Medical Inc., Japan)



8.1.6 FLUORESCENCE

Fluorescence is one of the most significant characteristics especially for esthetic composite restorations. The fluorescence of a composite should be assimilated into the tooth. The optimum amount of the fluorescent pigment was blended in the composition. The results show that the fluorescence of **CLEARFIL MAJESTY™ Esthetic** is the closest to that of natural tooth substance among the tested materials.

Fig. 24
Fluorescence (Source: Kuraray Medical Inc., Japan)



NATURAL TOOTH | CLEARFIL MAJESTY™ Esthetic | Filtek™ Supreme XT | Ceram.X™ | Tetric EvoCeram™ | Esthet-X™

8. PHYSICOCHEMICAL INVESTIGATION

8.2 CLEARFIL MAJESTY™ Posterior

Technical Data

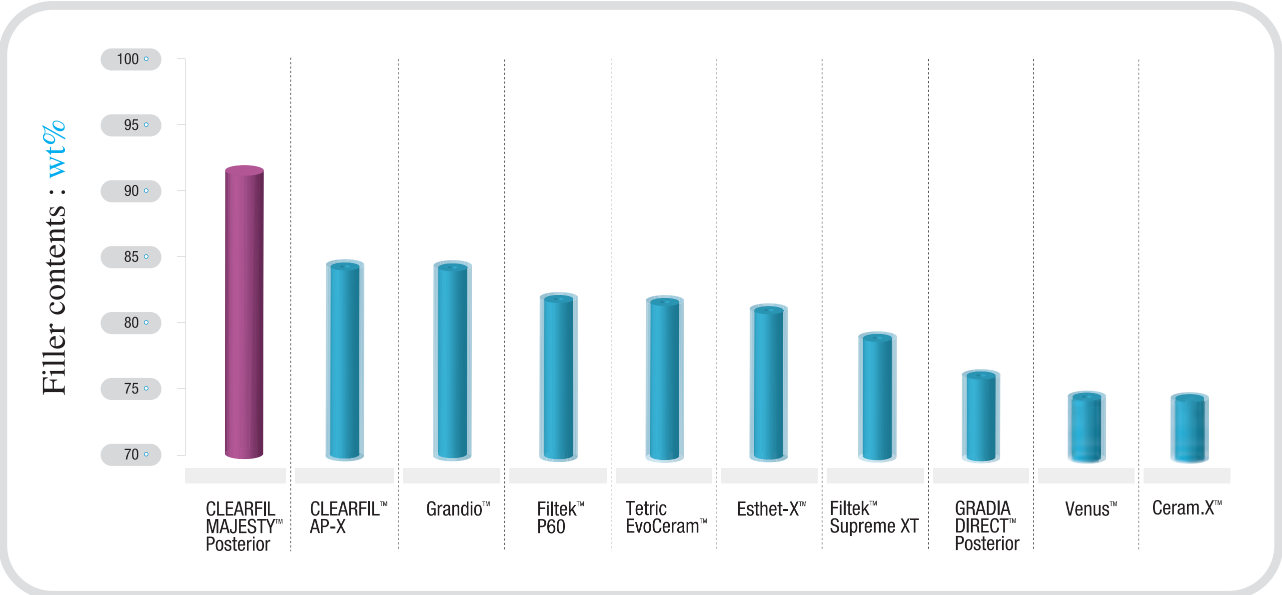
CLEARFIL MAJESTY™ Posterior

FILLER LOAD	*92 wt% (82 vol%)*
COMPRESSIVE STRENGTH	*504 MPa*
FLEXURAL FATIGUE LIMIT (UNIVERSITY OF ANTWERP)	*112.6 ± 5.6 MPa*
FLEXURAL STRENGTH (ISO4049 : 2000)	*177 MPa*
MODULUS OF ELASTICITY	*22.0 GPa*
VICKERS HARDNESS	*139 Hv*
WATER SORPTION (ISO4049 : 2000)	*9.7 μg/mm^3*
WATER SOLUBILITY (ISO4049 : 2000)	*< 1 μg/mm^3*
RADIOPACITY (ISO4049 : 2000)	*250 %Al*
VOLUMETRIC SHRINKAGE (ARCHIMEDES METHOD)	*1.5 vol%*
THERMAL EXPANSION COEFFICIENT	*15.0 10^{-6}/°C*
WEAR RESISTANCE (MODIFIED LEINFELDER METHOD)	*0.65 mm^3*

8.2.1 FILLER CONTENTS

High density inorganic filler load technology generates the three most significant characteristics for a posterior composite: high mechanical strength, low polymerization shrinkage and low thermal expansion coefficient. In order to achieve reliable posterior restorations, the aim is to create a posterior composite which has these superior physiochemical properties. The composite was placed in the centrifuging tube, and methanol was added. The components wich can be dissolved in methanol were removed from the composite by centrifugal separation. The dry weight of the precipitate is measured, and the weight percent calculated as filler content. The results show that the filler loading of **CLEARFIL MAJESTY™ Posterior** is the highest weight percentage (92 wt%) among the tested materials.

Fig. 25
Filler contents (Source: Kuraray Medical Inc., Japan)

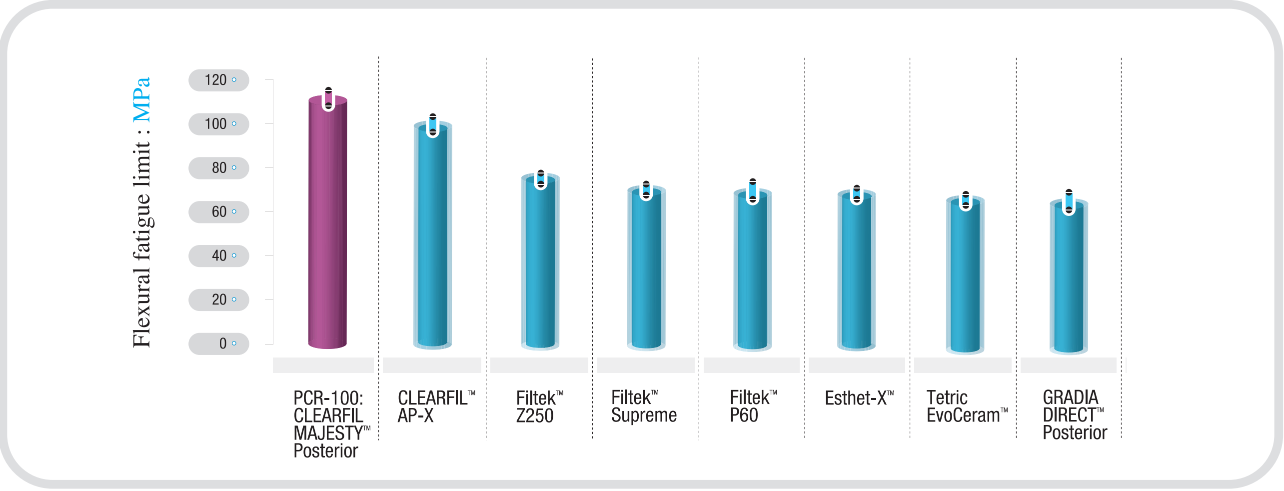


8.2.2 FLEXURAL FATIGUE RESISTANCE

The flexural fatigue resistance of a posterior composite is one of the most significant characteristics for the in-vitro evaluation. The experimental formulation **PCR-100 (Experimental CLEARFIL MAJESTY™ Posterior**, color A3) was tested for flexural fatigue resistance. Rectangular samples were prepared (length L = 40 mm, thickness T = 1.4 mm, width W = 5.2 mm), after light-curing for 3 minutes in a Unilux™ AC unit (Modified Unilux™ C, Heraeus Kulzer, The Netherlands) operating with visible light of 450-520 nm and with absolute time intervals. The samples were stored dry or wet in aq. dist., both at 37°C and tested accordingly. Testing was done after 1 month of storage. For the fatigue testing, the samples were loaded as in a transverse strength test, at a test frequency of 2 Hz, the upper limit of chewing frequency, to prevent undue protraction of the test duration. All testing was carried out at 37°C, to simulate oral temperature conditions. Load-control was preferred, thereby ensuring that the masticatory forces are constant. Furthermore, under a displacement-controlled regime eventual loss of stiffness of the tested composites would result in a decrease in load. All this was carried out in a proprietary developed fatigue machine. The flexural fatigue limit for the wet storage condition of the experimental formulation **PCR-100 (CLEARFIL MAJESTY™ Posterior)** showed higher strength than those of the tested conventional hybrid composites.

Fig. 26

Flexural fatigue limit (Source: Prof. Dr. Marc Braem, University of Antwerp, Belgium)



8.2.3 FLEXURAL STRENGTH AND MODULUS OF ELASTICITY

High flexural strength and modulus of elasticity are significant characteristics for a posterior composite. Posterior teeth are subject to strong chewing stress constantly. Especially tooth enamel, which has a high modulus, can keep its shape against the chewing stress, and has high modulus of elasticity (47– 84 GPa). Also, dentine shows 12-19 GPa [ref.: J. J. Dental. Mater. 1997, 16(6)]. The flexural strength and modulus of elasticity were measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Posterior** showed the highest flexural strength and modulus of elasticity among the tested materials.

Fig. 27

Flexural strength (ISO4049:2000, Source: Kuraray Medical Inc., Japan)

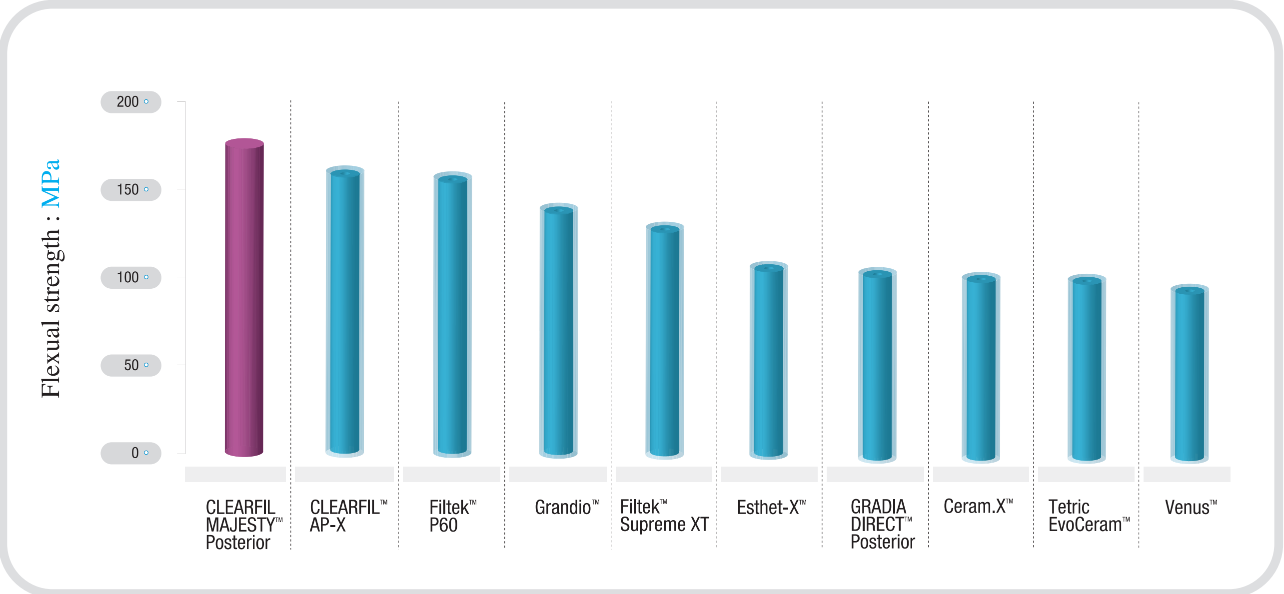
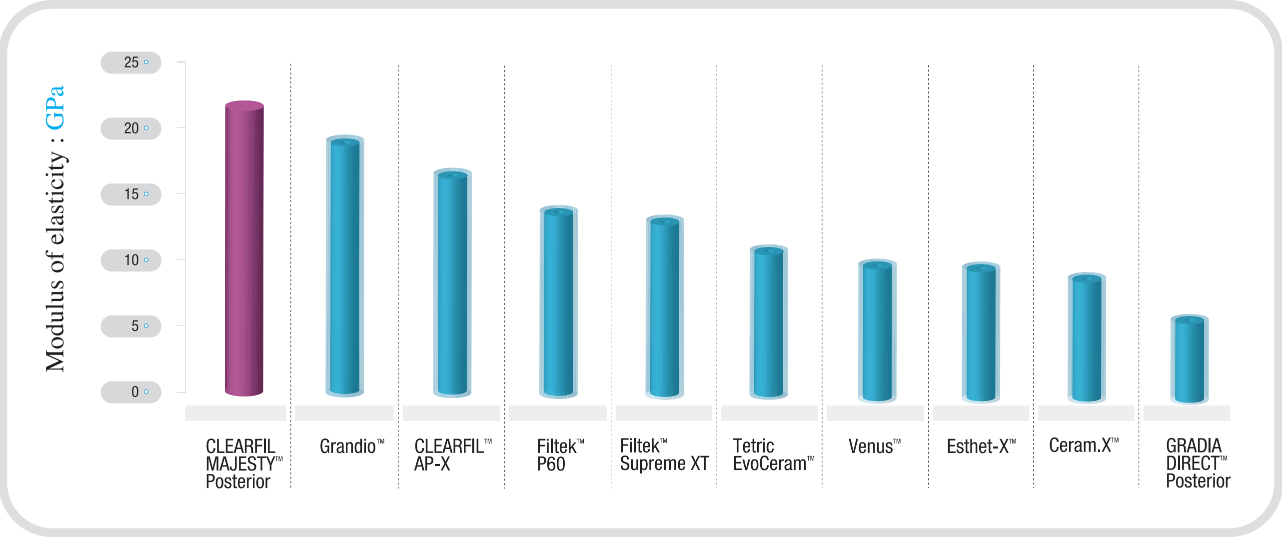
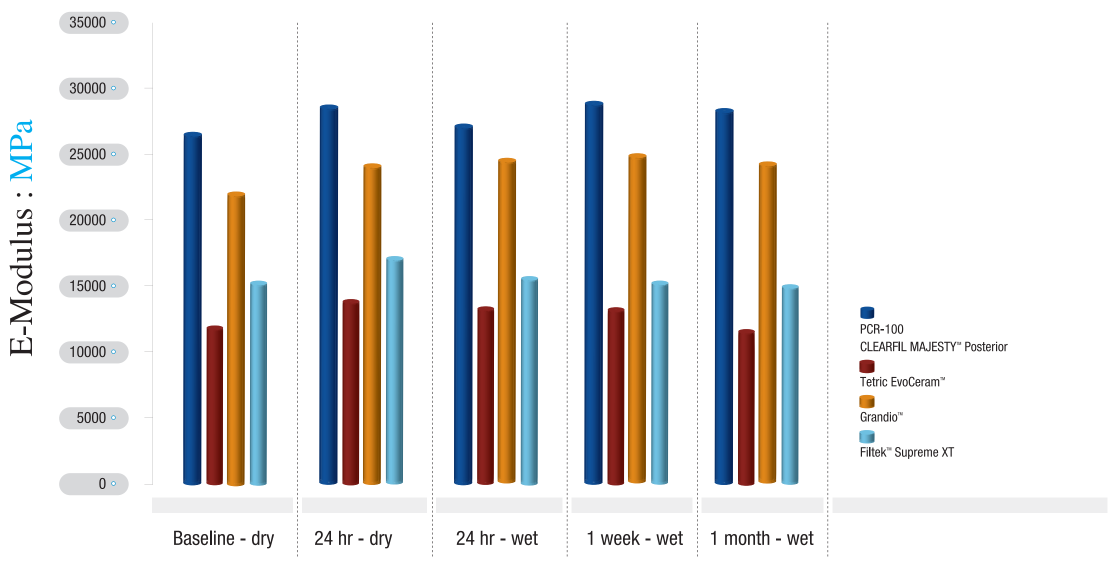


Fig. 28
Modulus of elasticity (Source: Kuraray Medical Inc., Japan)



Moreover, the modulus of elasticity (E-modulus durability) of **CLEARFIL MAJESTY™ Posterior** and commercialized composite resins were measured in accordance with the method in Dental Material 15 (1999).

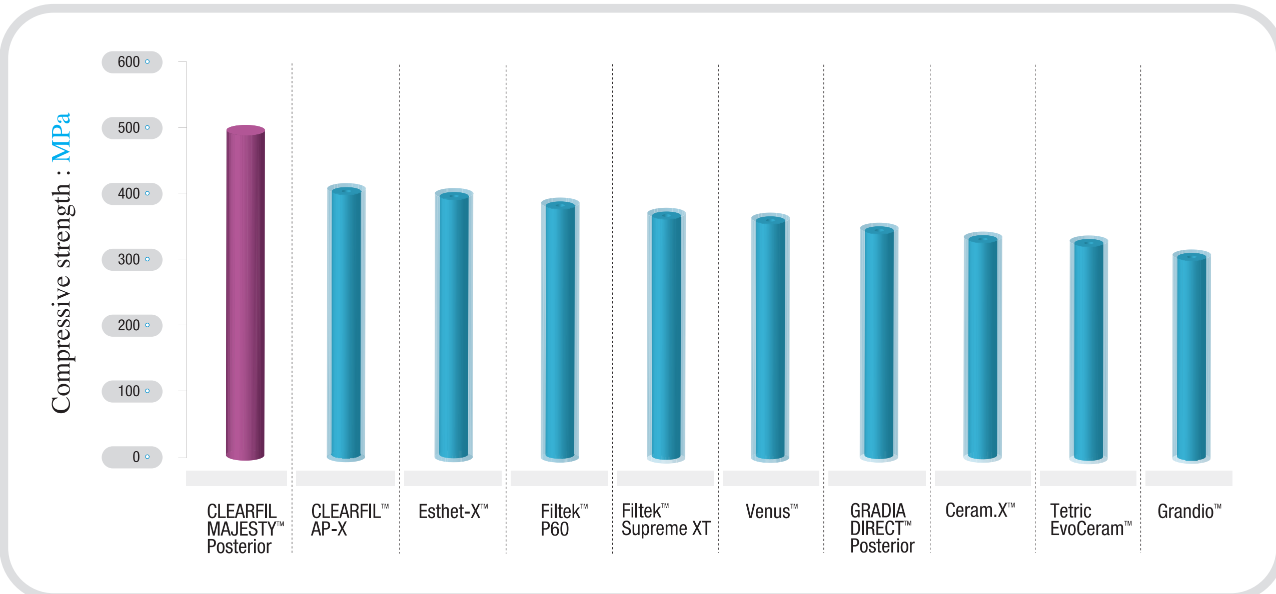
Fig. 29
Modulus of elasticity (Source: Prof. Dr. B. Van Meerbeek, University of Leuven, Belgium)



8.2.4 COMPRESSIVE STRENGTH

High compressive strength is one of the most significant characteristics for a posterior composite. The occlusal surface of posterior composite restorations suffers strong chewing stress throughout the lifetime of a load bearing restoration. Columnar specimens of 4 mm in diameter and 4 mm in height were made, and Autograph was used at cross head speed 2 mm/min. The results show that the compressive strength of **CLEARFIL MAJESTY™ Posterior** is the highest strength among the tested materials.

Fig. 30
Compressive strength (Source: Kuraray Medical Inc., Japan)



8.2.5 VICKERS HARDNESS AND WEAR RESISTANCE

High surface hardness of posterior composites is one of the significant characteristics for good wear resistance. Posterior composite restorations are subject to chewing loads and often parafunctional loading in the long term. The Vickers hardness of the composite surface was measured with the micro hardness testing machine [MVK-E; 200gf, 10 sec.] in accordance with ISO10477:2004 after immersion in water (37ºC) for 1 day. The results show that the Vickers hardness of **CLEARFIL MAJESTY™ Posterior** is the highest hardness among the tested materials. But the hardness is lower than that of human enamel (270–366 Hv) and is friendly towards antagonist enamel [ref.: J. J. Dental. Mater. 1997, 16(6)]. The wear resistance was evaluated by the modified Leinfelder-type wear test (load: 15.6 kg/cm2, repetition: 100,000 times). The abrasion of **CLEARFIL MAJESTY™ Posterior** was the least by volume among the tested materials.

Fig. 31

Vickers hardness (Source: Kuraray Medical Inc., Japan)

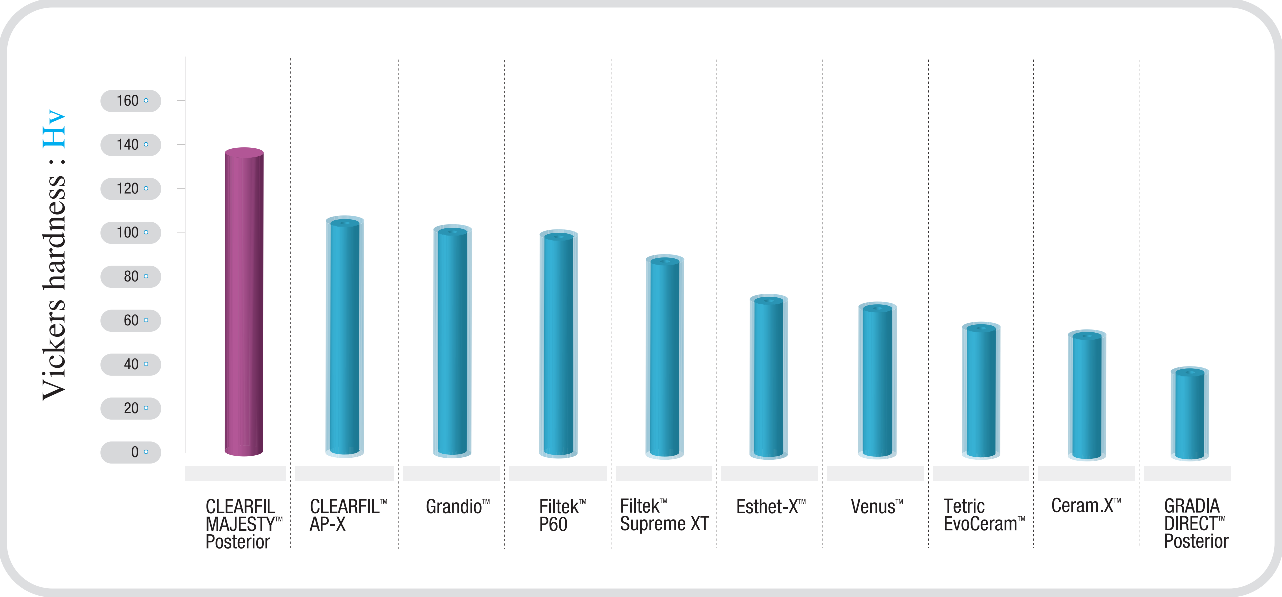
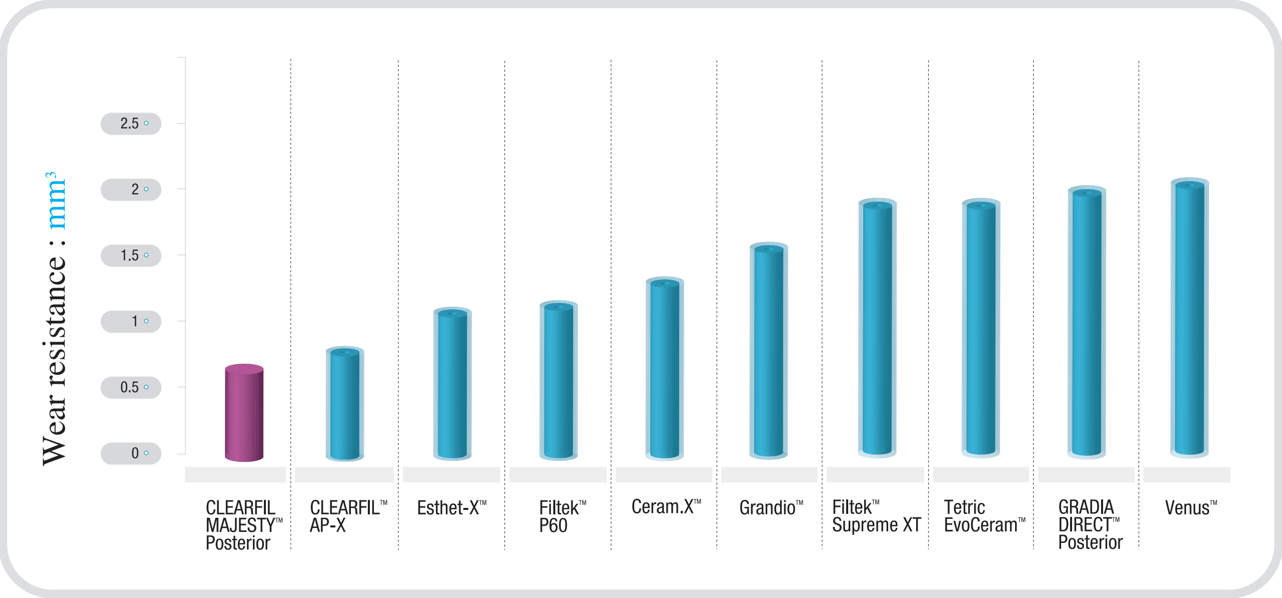


Fig. 32

Wear resistance (Source: Kuraray Medical Inc., Japan)

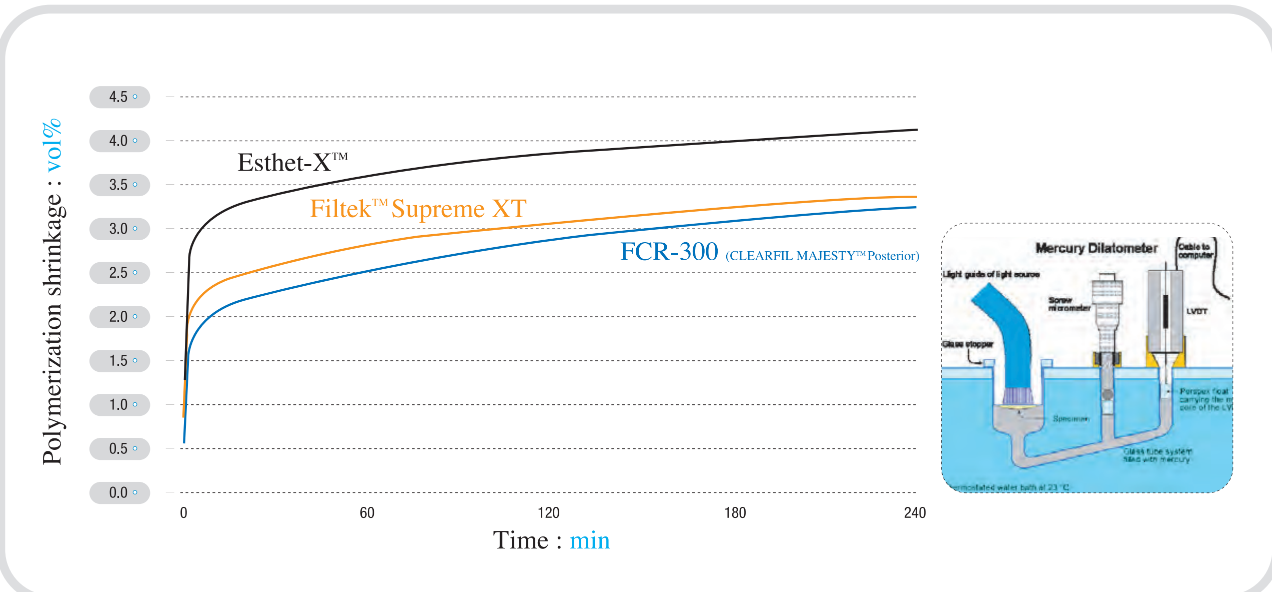


8.2.6 VOLUMETRIC POLYMERIZATION SHRINKAGE

For posterior restorations, cavities may be extensive and the adhesion interface may suffer from strong polymerization stressing during polymerization as a consequence. Even now, reducing the volumetric polymerization shrinkage of composites is one of the most important goals in product development. Moreover, the shrinkage stress at the adhesion interface might be reduced by the optimum selection of adhesive, light curing unit, filling method (increments), etc.

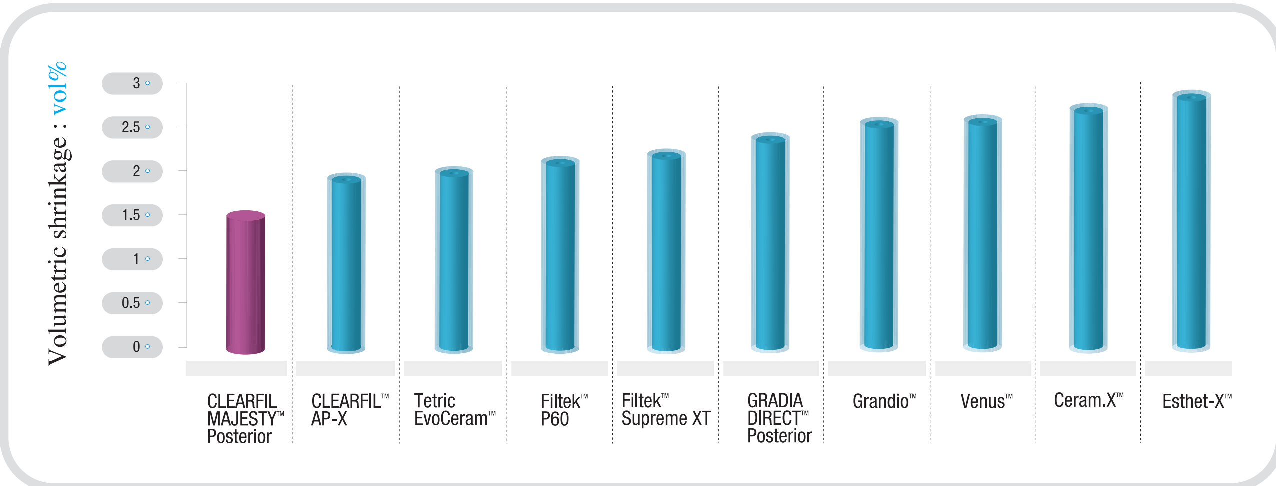
Setting shrinkage measurements were recorded continuously over a period of 4 hours at 23°C with a mercury dilatometer. A layer of high vacuum grease (Dow Corning Co, USA) was applied on the flat surface of the glass stopper for separation. An amount of approximately 300 mg of a composite paste was applied on the greased surface of the stopper and flattened to a thickness of approximately 1.5 mm. After the stopper was inserted into the dilatometer the specimen was light activated with an Elipar™ Highlight (3M Espe) for 40 s in Standard mode (750 mW/cm^2). Recording was started at the moment that the light source was switched on. The temperature of the dilatometer was 23.0°C. Of each material five specimens (n = 5) were measured over a period of 4 hours. After the specimens were removed from the dilatometer, the grease was washed off in ether and the density measured with the special equipment for density measurements of a Mettler Toledo (Mettler AT 261 Delta Range Mettler Instruments AG). The **Experimental CLEARFIL MAJESTY™ Posterior (PCR-100, color A3)** showed lower volumetric polymerization shrinkage than Esthet.X™, A2 (Dentsply Caulk) and Filtek™ Supreme XT, A2E (3M Espe).

Fig. 33
Volumetric polymerization shrinkage (Source: Dr. A.J. de Gee, ACTA, The Netherlands)



Polymerization shrinkage was measured by computing the specific gravity of samples before and after polymerization. For the measurement of specific gravity, an electronic hydrometer (A&D Ltd., AD-1653) that adopted the Archimedean method was used, and hexane was used as a medium in the measurement [ref.: Y.Hatsuoka, K. Yamamoto, M. Inoue, Japan. J. Conserv. Dent. 45(6), 1060~1066, 2002]. **CLEARFIL MAJESTY™ Posterior** showed the lowest volumetric polymerization shrinkage among the tested hybrid composites.

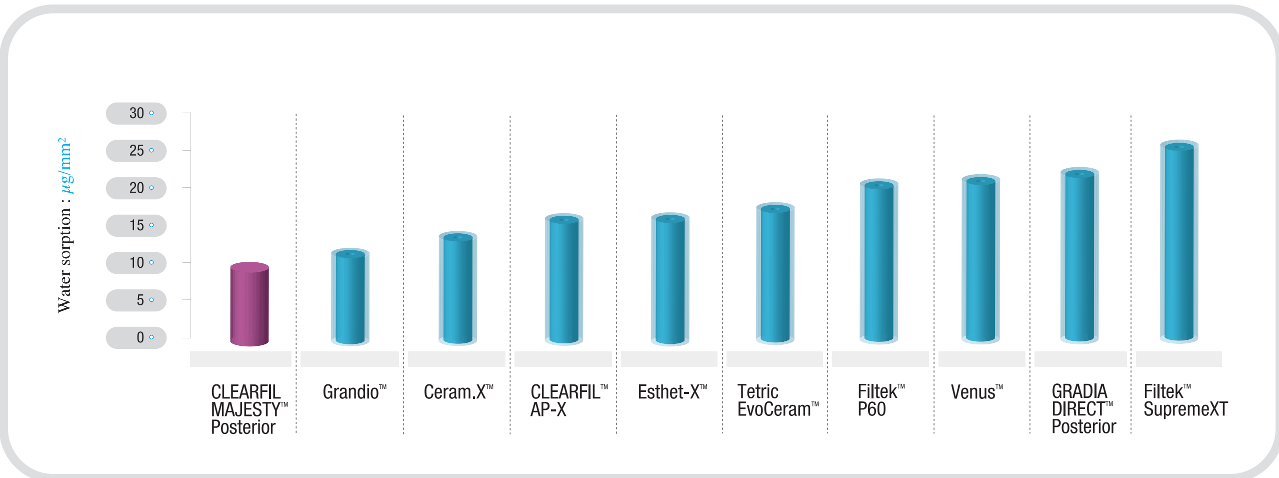
Fig. 34
Volumetric polymerization shrinkage (Source: Kuraray Medical Inc., Japan)



8.2.7 WATER SORPTION

Low water sorption of posterior composites is one of the most significant characteristics for the restoration of large cavities. The organic matrix of the composite absorbs water in the long term. High water sorption of composite is cited as a factor in the deterioration of physical characteristics and secondary caries. The water sorption was measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Posterior** showed the lowest water sorption among the tested materials. **CLEARFIL MAJESTY™ Posterior** is suitable for posterior restoration thanks to its hydrophobic character.

Fig. 35
Water sorption (Source: Kuraray Medical Inc., Japan)

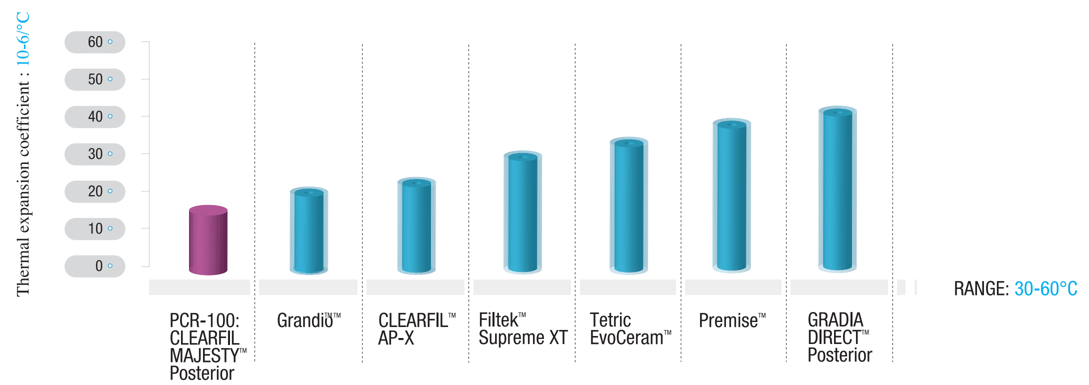


8.2.8 THERMAL EXPANSION COEFFICIENT

The restored composite suffers thermal stress in the mouth in the long term. A low thermal expansion coefficient of the posterior composite is one of the most important characteristics for posterior restorations. The difference of thermal expansion between restoration material and tooth generates the strain at the adhesion interface. The strain stress is cited as a factor in the micro leakage and marginal failure. A composite's thermal expansion coefficient which is similar to tooth substance (enamel: 11.4 10^{-6}/ºC, dentine; 8.0-8.3 10^{-6}/ºC) is the goal [ref.: J. J. Dental. Mater. 1997, 16(6)]. The thermal expansion coefficient (Range: 30-60ºC) was evaluated by JFE Techno-Research Corp. in 2006. The results show that the thermal expansion coefficient of **CLEARFIL MAJESTY™ Posterior** is the lowest among the tested materials. The thermal expansion coefficient is approximately that of enamel.

Fig. 36

Thermal expansion coefficient (Source: JFE Techno- Research Corporation, Japan)



8. PHYSICOCHEMICAL INVESTIGATION

8.3 CLEARFIL MAJESTY™ Flow

Technical Data

CLEARFIL MAJESTY™ Flow

FILLER LOAD	*81 wt% (62 vol%)*
COMPRESSIVE STRENGTH	*329 MPa*
FLEXURAL STRENGTH (ISO4049 : 2000)	*145 MPa*
MODULUS OF ELASTICITY	*10.5 GPa*
VICKERS HARDNESS	*78 Hv*
WATER SORPTION (ISO4049 : 2000)	*7.7 µg/mm^3*
WATER SOLUBILITY (ISO4049 : 2000)	*< 1 µg/mm^3*
RADIOPACITY (ISO4049 : 2000)	*290 %Al*
LINEAR SHRINKAGE	*1.88 lin%*
THERMAL EXPANSION COEFFICIENT	*36.3 10^{-6} /°C*
WEAR RESISTANCE (MODIFIED LEINFELDER METHOD)	*0.75 mm^3*

8.3.1 FLEXURAL STRENGTH AND MODULUS OF ELASTICITY

Flowable composite resin is especially suited for small and tricky cavities in terms of minimum intervention, because universal hybrid composite is too viscous. Moreover, flowable composite resin is appropriate as a lining material. But the indication of conventional flowable composite resin is limited due to the low mechanical strength based on the low filler load. The flexural strength and modulus of elasticity were measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Flow** (filler contents: 81 wt%, 62 vol%) showed the highest flexural strength (145 MPa) among the tested flowable composites. **CLEARFIL MAJESTY™ Flow** also showed a high modulus of elasticity (10.5 GPa). The mechanical property of **CLEARFIL MAJESTY™ Flow** is comparable to high mechanical hybrid composites.

Fig. 37

Flexural strength (Source: Kuraray Medical Inc., Japan)

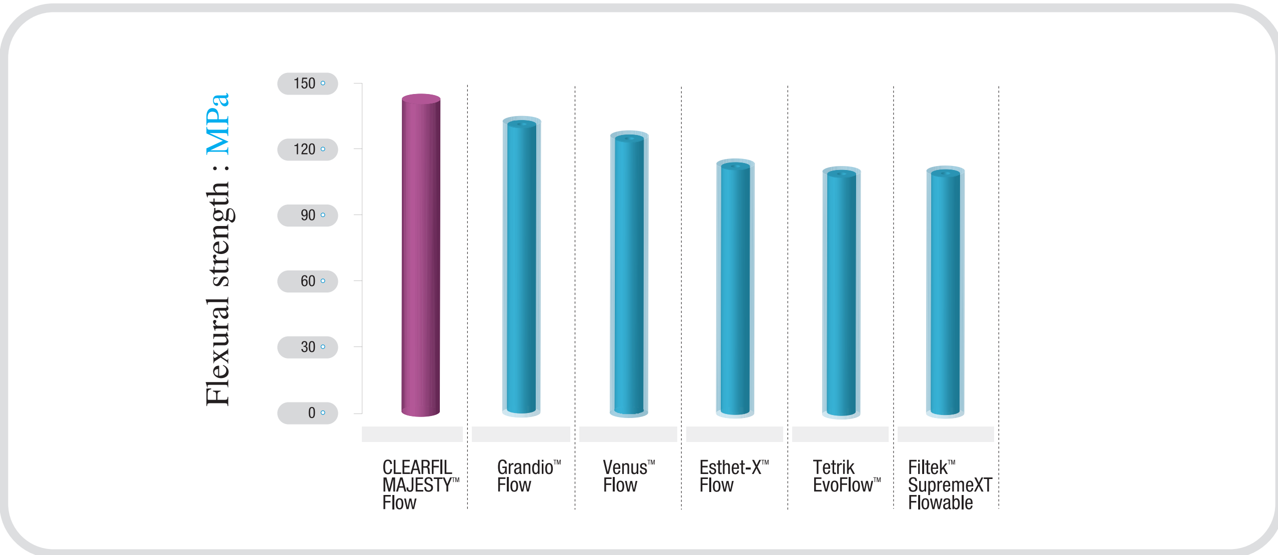
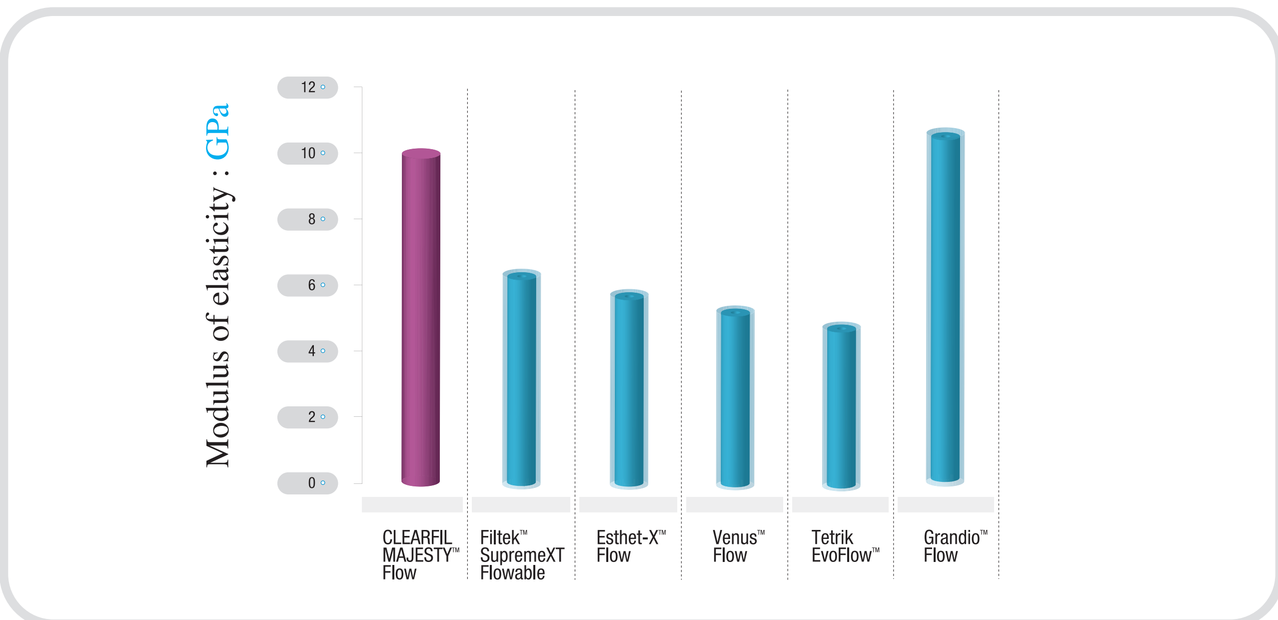


Fig. 38

Modulus of elasticity (Source: Kuraray Medical Inc., Japan)



8.3.2 VICKERS HARDNESS AND WEAR RESISTANCE

CLEARFIL MAJESTY™ Flow achieved the high filler load (81 wt%, 62 vol%) due to the proprietary filler surface technology »**Nano Dispersion Technology**«. A flowable composite also requires a high surface hardness as a significant characteristic for the wear resistance. The Vickers hardness of the composite surface was measured with the microhardness testing machine [MVK-E; 200gf, 10 sec.] in accordance with ISO10477:2004 after immersion in water (37ºC) for 1 day. The results show that the Vickers hardness of **CLEARFIL MAJESTY™ Flow** is the highest of the tested flowable composite resins. The wear resistance was evaluated by the modified Leinfelder-type wear test (load: 15.6 kg/cm², repetition: 100,000 times). The abrasion of **CLEARFIL MAJESTY™ Flow** was the least by volume among the tested flowable composites and was comparable to conventional hybrid composites. The high filler load present in this composite does not limit its indication for use.

Fig. 39
Vickers hardness (Source: Kuraray Medical Inc., Japan)

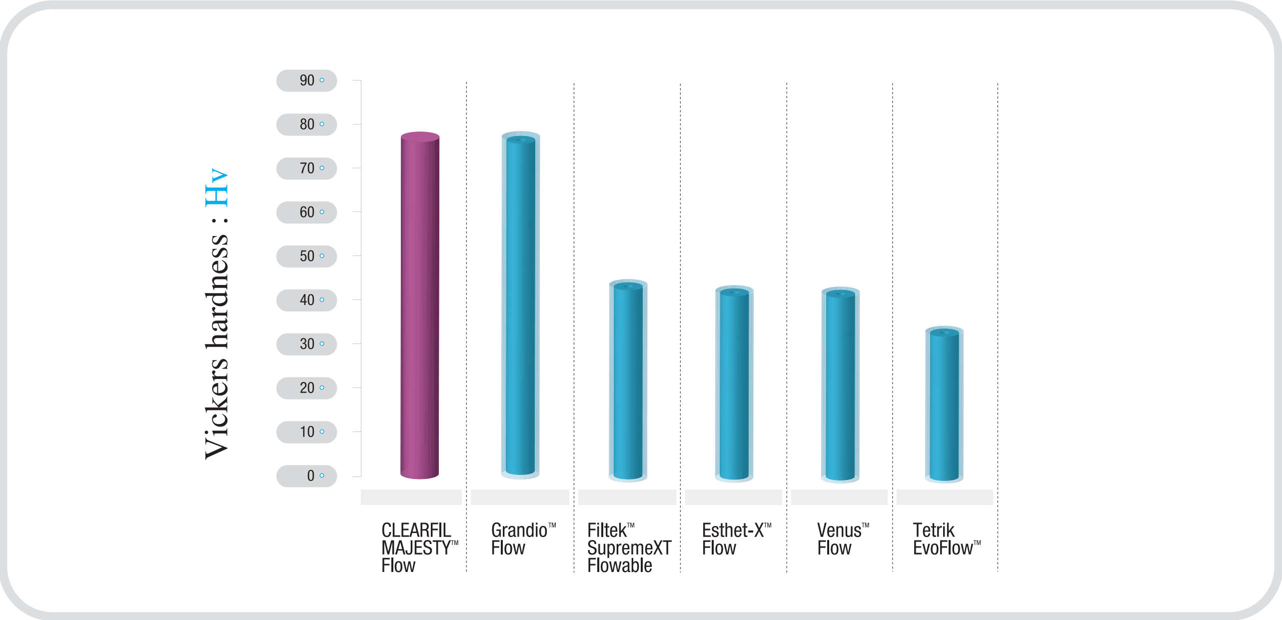
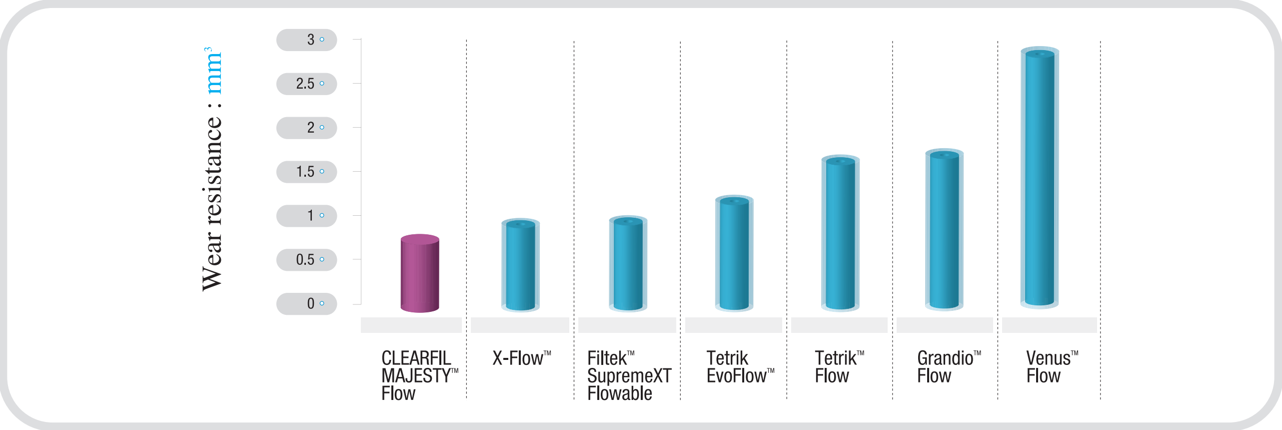


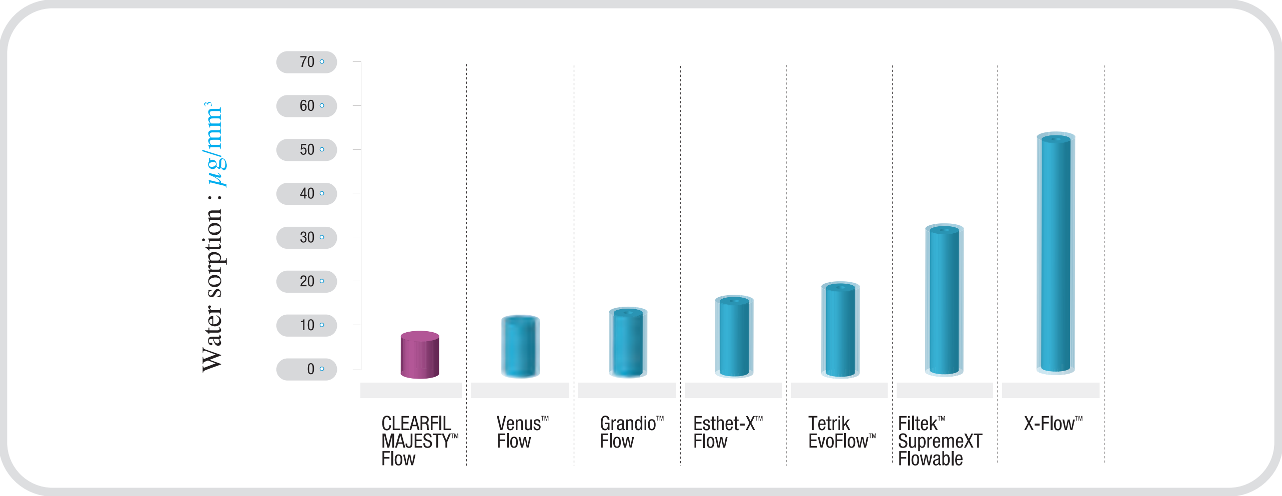
Fig. 40
Wear resistance (Source: Kuraray Medical Inc., Japan)



8.3.3 WATER SORPTION (ISO4049:2000)

The disadvantages of conventional flowable composites are their lower inorganic filler contents. The matrix of the flowable composite absorbs relatively generous amounts of water in the long term. High composite water sorption is cited as a factor in the deterioration of physical characteristics and secondary caries. The water sorption was measured in accordance with ISO4049:2000. **CLEARFIL MAJESTY™ Flow** showed the lowest water sorption among the tested flowable composite resins, and is especially suitable for sealing adhesive/dentine interfaces.

Fig. 41
Water sorption (Source: Kuraray Medical Inc., Japan)



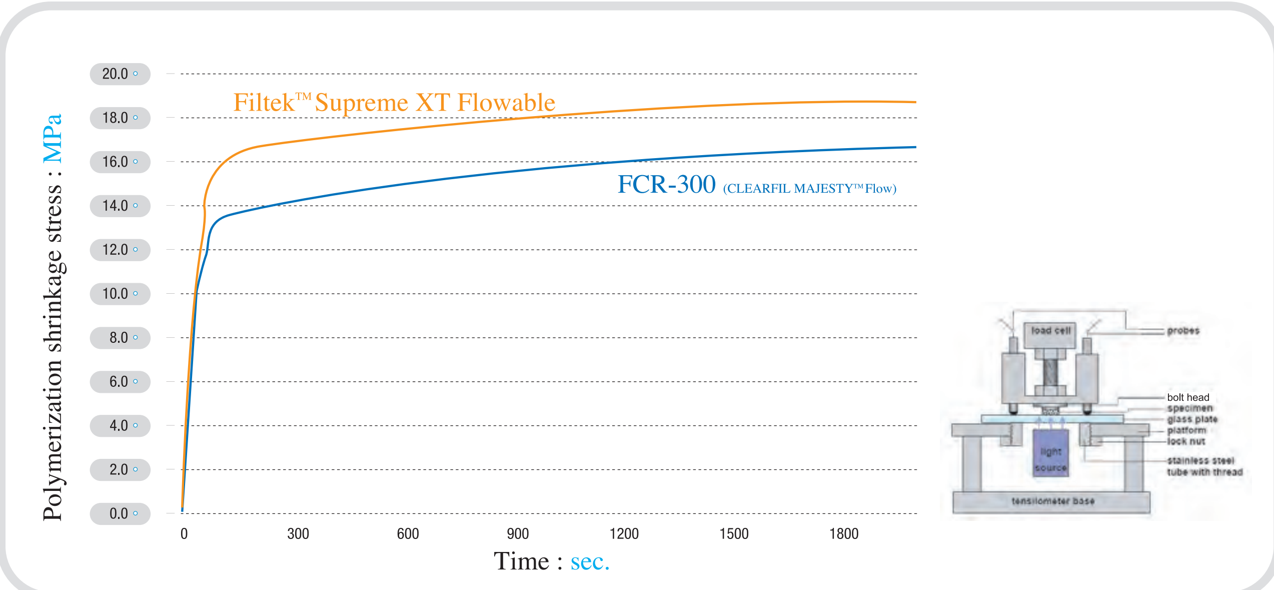
8.3.4 SHRINKAGE STRESS AND POLYMERIZATION SHRINKAGE

Flowable composite resins are used for a huge variety of clinical cases thanks to the flexible paste properties. The flexible characteristics makes it possible to reduce the polymerization shrinkage stress. **CLEARFIL MAJESTY™ Flow** combines the flexible characteristic with excellent physical properties of the high filler loaded composition.

Shrinkage stress

The test setup was placed in an Instron 6022 Tensilometer. Composite paste was inserted between the glass plate and the flat surface of the steel bolt head and adhered to both these surfaces. During light curing and a period of 30 min afterwards, the shrinkage stress development was measured, while the distance between the glass and the steel bolt head was kept constant. This simulated a restoration in a fully rigid situation where the cavity walls cannot yield to the contraction forces. The **Experimental CLEARFIL MAJESTY™ Flow** (FCR-300, color A3) showed lower shrinkage stress than Filtek™ Supreme XT Flowable, A3 (3M Espe).

Fig. 42
Shrinkage stress (Source: Dr. A.J. de Gee, ACTA, The Netherlands)

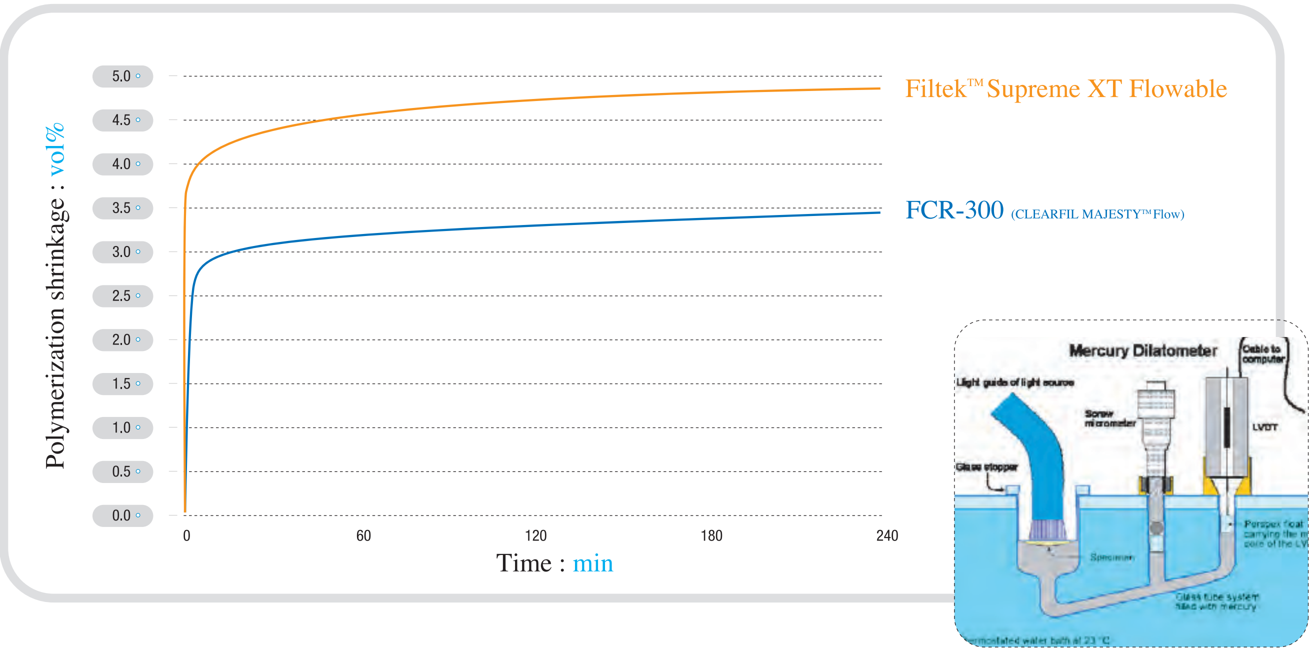


Volumetric polymerization shrinkage

Setting shrinkage measurements were recorded continuously over a period of 4 hours at 23°C with a mercury dilatometer. To avoid the running of low viscous material (like flowing continuously) between the stopper and the cylinder shaft of the specimen compartment, these materials had to be "packed" in sealed plastic bags. Thin plastic foil from litterbags was used to prepare these bags. The bottom edge of such a litterbag was cut off and the long side with the sharp crease (folding line) was formed into a tunnel sharp and heat-sealed at the long side. An amount of approximately 300 mg of a flowable material was contained in a plastic bag, which was placed with its flat bottom onto the bottom side of the glass of the stopper. After the stopper was inserted into the dilatometer the specimens were light cured for 40 s with an Elipar™ Highlight (Espe) in Standard mode (750 mW/cm^2). Recording was started at the moment that the light source was switched on. The temperature of the dilatometer was 23.0°C (±0.05°C). Each material from five specimens (n = 5) were measured over a period of 4 hours. After the specimens were removed from the dilatometer, the density was measured with the special equipment for density measurements of a Mettler Toledo (Mettler AT 261 Delta Range Mettler Instruments AG). The **Experimental CLEARFIL MAJESTY™ Flow** (FCR-300, color A3) showed lower volumetric polymerization shrinkage than FiltekTM Supreme XT Flowabel, A3 (3M Espe).

Fig. 43

Volumetric polymerization shrinkage (Source: Dr. A.J. de Gee, ACTA, The Netherlands)

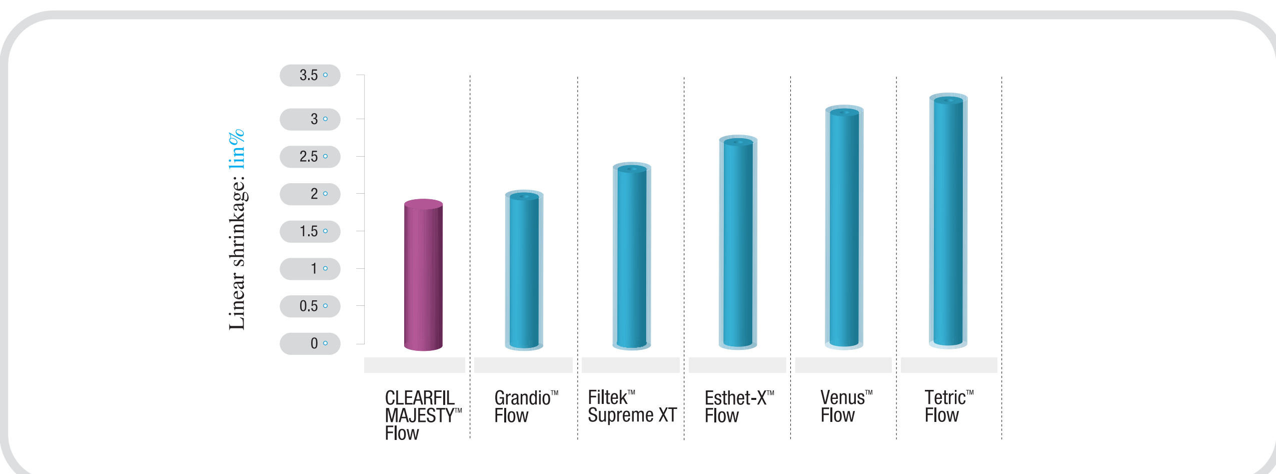


Linear shrinkage

Flowable composite resins are used for a huge variety of clinical cases thanks to the flexible paste properties. The flexible characteristics make it possible to reduce the polymerization shrinkage stress. **CLEARFIL MAJESTY™ Flow** is a high filler loaded but flowable composite resin. The resin paste was filled in the mold (ϕ6mm x 4mm). Linear polymerization shrinkage was measured using a CCD laser displacement meter (LK-G30, KEYENCE). The results show that the linear shrinkage of **CLEARFIL MAJESTY™ Flow** is the lowest among the tested flowable composite resins.

Fig. 44

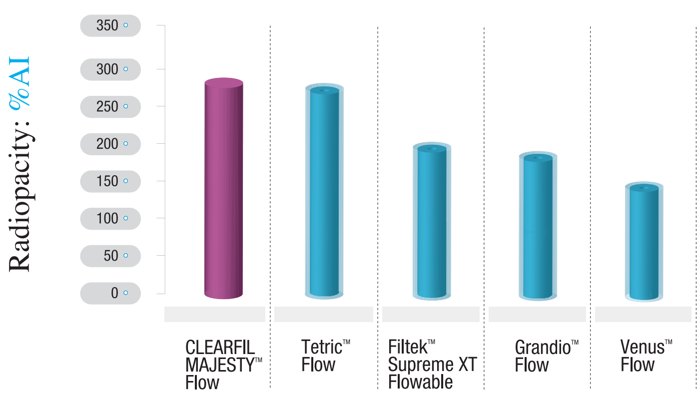
Linear shrinkage (Source: Kuraray Medical Inc., Japan)



8.3.5 RADIOPACITY

Conventional flowable composite resins show lower radiopacity due to their low filler loading. **CLEARFIL MAJESTY™ Flow** contains a great deal of barium glass filler (average: 3 µm) in the composition using the proprietary filler surface technology **»Nano Dispersion Technology«.** The characteristic is particularly important to differentiate from enamel, dentine and caries. The radiopacity was measured in accordance with ISO4049:2000. The results show that the radiopacity of **CLEARFIL MAJESTY™ Flow** is the highest (290 %Al) among the tested flowable composite resins. The innovative **»Nano Dispersion Technology«** also allows **CLEARFIL MAJESTY™ Flow** to be easily detected on dental x-rays.

Fig. 45
Radiopacity (Source: Kuraray Medical Inc., Japan)

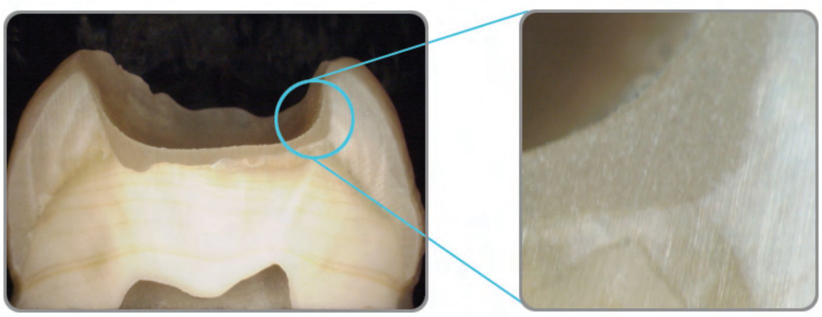


8.3.6 PASTE CHARACTERISTICS AND HANDLING PROPERTIES

The paste characteristics are closely related to the handling properties in clinical situation. **CLEARFIL MAJESTY™ Flow** has excellent wetability and does not stick to instruments. The paste shows no runny viscosity and does not slump out of Class V cavitites. The paste additionally has a high consistency due to the flexible paste properties. Therefore, **CLEARFIL MAJESTY™ Flow** is especially suited for an intricate cavity from the viewpoint of minimum intervention. It is easy to apply the filling material into the corners of the cavity and to seal the adhesive/dentine interface.

Fig. 46
The filling test with a class V cavity model

Fig. 47
The image of the cross section of a cavity covered with one layer of **CLEARFIL MAJESTY™ Flow**



The special dispenser and nozzle developed for **CLEARFIL MAJESTY™ Flow** makes it possible to control the quantity of necessary paste easily. The dispensed paste contains the least voids thanks to the newly developed syringe.

Fig. 48
Newly developed ergonomic syringe

9. RECOMMENDATIONS FOR POLISHING

CLEARFIL MAJESTY™ Esthetic

1) Shaping

Shape overall contour and marginal line smoothly using diamond point (fine). Using diamond point is strongly recommended. **CLEARFIL MAJESTY™ Esthetic** makes it difficult to shape CR by clogging especially for White point.

2) Finishing

Finish smooth surface using diamond point (super fine) or carbide bar (16 blades or 30 blades).

3) Polishing

The routine procedure gives sufficient gloss. The following is one example of a polishing procedure.
Polish using **CompoMaster™** (Shofu). Disc, **Sof-Lex™** (3M Espe), **Super-Snap™** (Shofu) etc. is recommended for flat surfaces. If a glossier surface is necessary, polish using **Ultra II** (Shofu, diamond particle containing polishing agent) with **Super-Snap™ Buff Disc** (Shofu) or polishing brush.

CLEARFIL MAJESTY™ Posterior and **CLEARFIL MAJESTY™ Flow**

1) Shaping

Develop the overall contour and marginate the restoration smoothly using a diamond point (fine).

2) Finishing

Finish smooth surfaces using diamond point (super fine) or carbide bar (16 blades or 30 blades).

3) Polishing

Polish to a glossy surface with **CompoMaster™** (Shofu). If a glossier surface is necessary, polish using **Ultra II** (Shofu, diamond particle containing polishing agent) with **Super-Snap™ Buff Disc** (Shofu) or a polishing brush.

10. CLINICAL STUDY *Dr. Toshimoto Yamada, DDS, PhD, Toranomon Hospital, Japan*

This study is a clinical trial of the self-etching adhesive **CLEARFIL™ S^{3}BOND (CLEARFIL™ tri-S bond)** together with a resin-based restorative material **CLEARFIL MAJESTY™** (the product name in Japanese market). A total of 30 restorations were placed in 30 human subjects in caries-free Class V eroded/abraded areas in permanent teeth.

The reports after 12 months recorded the satisfactory status of all restorations following recovery from the operative procedure of placement.

At the 12 month recall all restorations that were reviewed were satisfactory in all clinical criteria specified. No failures have so far been observed at all recalls and the Kaplan-Meier probability of survival rate for these restorations after 12 months is 1.00.

Objective of the investigation

This trial will determine the short-term efficacy of the self-etching adhesive **CLEARFIL™ S^{3}BOND (CLEARFIL™ tri-S bond)** as a dentine and enamel adhesive material, in a group of patients under conditions which represent its normal conditions of use.

Design of the investigation

The investigation is a short-term, uncontrolled trial. The design is based on the guidelines of the American Dental Association for assessment of dentine and enamel adhesive materials of 2001. The study originally set out to examine the performance of cervical restorations of at least 30 subjects at recalls at baseline, 3 months, 6 months, 12 months, and 18 months.

History of the study

During the months of March and May 2006, 30 trial restorations were placed in a total of 30 patients using the self-etching adhesive **CLEARFIL™ S^{3}BOND (CLEARFIL™ tri-S bond)** in combination with the resin-based restorative **CLEARFIL MAJESTY™**. Two operators in general dental practice placed all the restorations. Baseline records were made by the practitioners immediately after placement. Patients were followed up routinely at recall intervals that were appropriate to their oral health status, and at each recall the restorations were evaluated for clinical acceptability.

Discussion

It is noted to be interesting that all the restorations showed Alpha rating 12 months after placement, and were deemed to be clinically satisfactory in all aspects examined. It seems that the observation period was relatively short but according to the laboratory studies the bond strength of this resin bonding system was quite high, as much as 20 MPa to bovine enamel and dentine. Also the FE-SEM study revealed that the tight interfacial junction was obtained between the resin and enamel/dentine, creating the hybrid layer at the dentine interface. These findings would support the clinical results in this study.

Conclusion

The restoration system: a self-etching adhesive **"CLEARFIL™ S³BOND"** and a resin-based restorative material **"CLEARFIL MAJESTY™"** has been demonstrated to be a satisfactory dentine and enamel adhesive material for the restoration of caries-free Class V eroded/abraded areas in permanent teeth over a period of 12 months.

CRITERION		BASE LINE	6 MONTHS	12 MONTHS
RESTORATION	*A: satisfactory* *B: moderate* *C: severe*	*100% A*	*100% A*	*100% A*
MARGINAL DISCOLORATION	*A: none* *B: potential failure* *C: failure*	*100% A*	*100% A*	*100% A*
MARGINAL ADAPTATION	*A: excellent* *B: good* *C: fair* *D: poor*	*100% A*	*100% A*	*100% A*
SURFACE TEXTURE	*A: smooth* *B: slightly rough* *C: rough*	*100% A*	*100% A*	*100% A*
ABRASION	*A: none* *B: slight* *C: severe*	*100% A*	*100% A*	*100% A*
MARGINAL FRACTURE	*- : none* *+ : detected*	*100% -*	*100% -*	*100% -*
BODY FRACTURE	*- : none* *+ : detected*	*100% -*	*100% -*	*100% -*
SECONDARY CARIES	*- : none* *+ : detected*	*100% -*	*100% -*	*100% -*
PAIN*	*A: none* *B: slight* *C: severe*	*100% A*	*100% A*	*100% A*
IRRITATION**	*- : none* *+ : detected*	*100% -*	*100% -*	*100% -*

* Spontaneous, cold water, hot water, occlusal
** Gingival, soft tissue

11. LITERATURE

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NOTE:

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