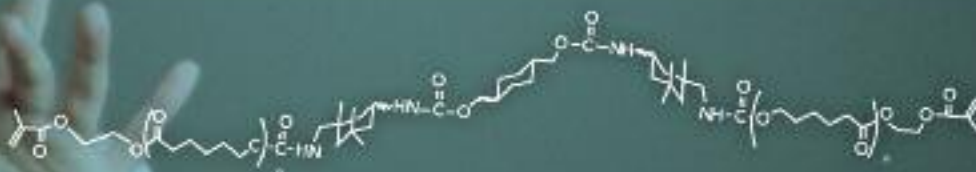




KALORE™

THE SCIENCE BEHIND THE SMILE™



The DuPont Monomer

TECHNICAL MANUAL

GC

Over 100 scientists, chemists and researchers are focused on the research and development of dental materials, fostering innovation and technological advances, utilizing a new, state-of-the-art facility.

"As a leading dental company, we strongly feel the need to act as a bridge builder between dentistry and other medical specialties as well as our industry, and properly transfer their technologies into custom-made technologies useful for the further improvement of oral health of people throughout the world."

- Mr. Makoto Nakao, President & CEO, GC CORPORATION.
Dental Economics - August 2007.

GC



Fast-paced and creative advances are enabled by the open layout and "communication loop" at the new research facility.



A Legacy of Quality and Innovation

- In 2000, GC Corporation became the first company in the dental industry to receive the Deming Application Prize.
- In 2004, GC became the 18th company in the world to receive the "Japan Quality Medal," the highest echelon in quality control in Japan.
- GC Corporation became one of the earliest to receive an ISO 9001 certification in 1994.
- In April 2004, GCC received the ISO 13485 certification, which specifically provides for the quality assurance of medical devices. GC was the first dental equipment/material manufacturer to receive either certification.
- In the 5th Quality Management Survey conducted in 2009 by Nihon Keizai Shimbun Inc. and Union of Japanese Scientists and Engineers, GC was ranked 4th for "Quality Assurance and Personnel Cultivation (Education)" and "Development of New Products," behind Panasonic Corporation (1st), FUJIFILM HOLDINGS (2nd) and SHARP CORPORATION (3rd).

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1.0 INTRODUCTION

GC Corporation is a world leader in the field of crown and bridge composite resins, with products that include GRADIA®, a micro-ceramic composite, and GRADIA® FORTE – a nano-hybrid composite. Expertise in durable, aesthetic indirect composites that were excellent alternatives to porcelain led GC Corporation to develop GRADIA® DIRECT – a direct composite material offering easy handling and unrivaled aesthetics using one shade. GRADIA DIRECT rapidly became the composite of choice for many dental clinicians worldwide. Building on this technology, new objectives included the development of next generation, state-of-the-art aesthetic direct composite materials. Since benchmark research clearly indicated that monomer technology is more advanced in other industries, it was decided to seek an industrial partner to co-develop new innovative monomers suitable for use in clinical dentistry. On August 21, 2007, GC Corporation signed an agreement with DuPont, a world leader in the development and manufacturing of polymers and synthetic materials such as Nylon[†], Lycra[†], Teflon[†] and Kevlar[†]. As a result of this partnership, a proprietary new monomer – DX-511 – has been developed for direct composites. DX-511 is a key component of GC Corporation's new low shrinkage (stress) direct composite, KALORE™.

2.0 PRODUCT DESCRIPTION

KALORE is a visible-light-cured radiopaque nano-sized hybrid resin composite containing high-density radiopaque (HDR) pre-polymerized fillers and DX-511. Its unique composition enables the creation of anterior and posterior direct composite restorations with high polish, high wear resistance, low polymerization shrinkage (stress) and durability. The non-sticky formulation provides for easy handling and shaping, and its initial wettability to tooth surfaces eases its adaptation to preparation walls. KALORE retains its shape, does not slump and offers sufficient working time without premature setting of the material under the operatory light. KALORE is available in a range of shades that result in highly aesthetic, natural-looking restorations. KALORE offers the clinician multiple advantages:



- Low polymerization shrinkage
- Low polymerization shrinkage stress
- Excellent aesthetics
- Easy handling
- Adequate working time
- Durability
- High wear resistance
- High polish and gloss

3.0 INDICATIONS FOR USE

- Direct restorative for Class I, II, III, IV and V cavities
- Direct restorative for wedge-shaped defects and root surface cavities
- Direct restorative for veneers and diastema closure

4.0 COMPOSITION

KALORE consists of a matrix, fillers, photo initiator and pigment (Table 1).

4.1 Matrix

The matrix contains a mixture of urethane dimethacrylate (UDMA), dimethacrylate co-monomers and DX-511 monomer. KALORE does not contain bis-GMA.

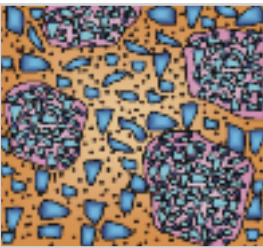
4.2 Fillers

Newly developed high-density radiopaque (HDR) pre-polymerized fillers are at the core of the KALORE filler system. These fillers contain 60% wt. 400 nm nano-sized modified strontium glass and 20% wt. 100 nm lanthanoid fluoride. The modified strontium glass reinforces the filler’s strength and surface hardness, provides high polishability, and matches the refractive index of the UDMA resin matrix, thereby offering improved aesthetics (the barium glass commonly used in composites has a higher refractive index than UDMA resin, resulting in decreased translucency and poorer aesthetics). Lanthanoid fluoride is added to increase the radiopacity. The combination of 17 µm particle size HDR filler and 30% wt. volume guarantees optimal handling. 700 nm strontium glass particles, fluoroaluminosilicate glass and nano-sized silica are dispersed between the HDR fillers (Fig. 1). The modified strontium glass and fluoroaluminosilicate glass each have slightly differing refractive indices to provide complex light reflection and light scattering for a chameleon effect.

Table 1. Composition of KALORE.

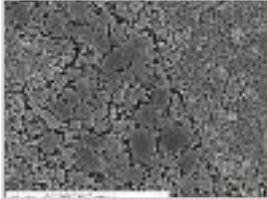
Components	Weight %
Matrix	18
Urethane dimethacrylate	
DX-511 co-monomers	
Dimethacrylate	82
Fillers	
Fluoroaluminosilicate glass	
Strontium glass	
Pre-polymerized filler	
Silicon dioxide	< 1
Other	
Photo initiator	< 1
Pigment	

Figure 1a. Structural drawing of the filler system.



- Pre-polymerized Filler (17µm)**
 - 400 nm strontium glass
 - 100 nm lanthanoid fluoride
- Inorganic Filler**
 - 700 nm strontium glass
 - 700 nm fluoroaluminosilicate glass
- Monodispersed silica**
 - 16 nm

Figure 1b. SEM image of the filler system.



4.3 Interface

The interface between the pre-polymerized fillers and the resin matrix is a critical factor. In KALORE there are three types of interactions at this interface that help to prevent early catastrophic failure. The three types of interactions are as follows:

1. Covalent bonds derived from C=C. Both the pre-polymerized fillers and methacrylate matrix monomers contain C=C groups which can cross-link with each other. Although the methacrylates are mostly cured, residual C=C groups still remain.
2. Hydrogen bonds from polar constituents, such as -OH, -NH, and -C=O.
3. Hydrophobic interactions between organic groups (e.g., alkyls). These interactions result in intimate contacts rather than strong bonds. Each contact is relatively moderate, however the total contribution of these contacts should be considered.

The silica surfaces are treated hydrophobically with dimethyl constituents, to attract the silica and matrix to each other and increase their intimate contact. Dimethyl-treated silica is also more stable than silica treated with methacryloxysilane, resulting in an improved shelf life with less risk of stiffening of the material during storage.

The fluoroaluminosilicate and strontium glasses used in KALORE are silanated.

4.4 Initiators

A combination of camphorquinone and amine is used as the catalyst. Light activation can be carried out with quartz halogen, plasma or LED curing units.

5.0 PHYSICAL PROPERTIES

KALORE has been formulated to reduce polymerization shrinkage and shrinkage stress while still providing excellent handling and aesthetics.

5.1 The Importance of Low Polymerization Shrinkage (Stress)

Low shrinkage and low shrinkage stress are important for several reasons. Shrinkage stress occurs when the resin matrix in composite resins shrinks in volume during polymerization, while the particles retain their pre-polymerization volume. The resulting stress at the filler and resin matrix interface remains within the cured composite resin and can lead to early replacement of restorations, as particles will be lost from the matrix. If shrinkage stress is high and exceeds the initial bond strength of the restoration, de-bonding may occur at the cavity wall resin interface. This can result in post-operative sensitivity and marginal leakage. Long-term, marginal leakage will often lead to replacement of the composite restoration. It has also been reported that if both the shrinkage stress and bond strength are high, tooth deformation and cuspal deflection can occur, and cracks can form in the tooth structure. We will first review the principles of polymerization shrinkage and technology used to reduce these.

5.2 Basic Principles of Shrinkage

Dental resin materials typically use dimethacrylate resin, which has a methacrylate group at each end of the monomer chain. Methacrylates contain two carbon-carbon double bonds and can easily form polymers as the double bonds are very reactive (Fig. 2).

During polymerization, the carbon-carbon double bond is broken by the catalyst, the monomers react with each other to form polymers, and the distance between the reacting monomers lessens. While the particles retain their pre-polymerization volume, the reduced distance between the reacting monomers results in volume loss due to shrinkage (Fig. 3).

Figure 2. Dimethacrylate resin.

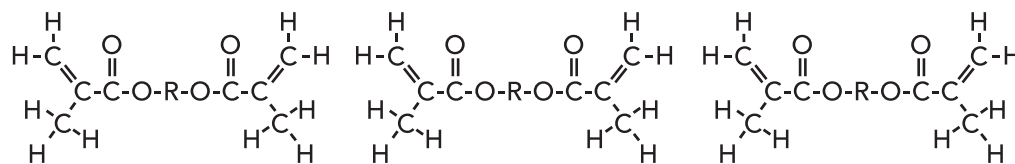
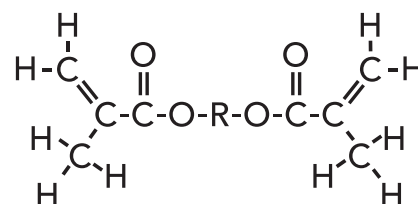


Figure 3a. Dimethacrylate resin monomer molecules in the resin matrix.

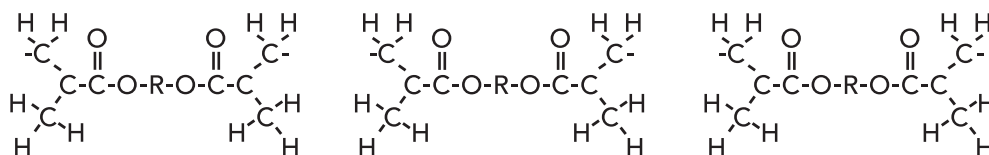


Figure 3b. The carbon-carbon double bond is broken by the catalyst.

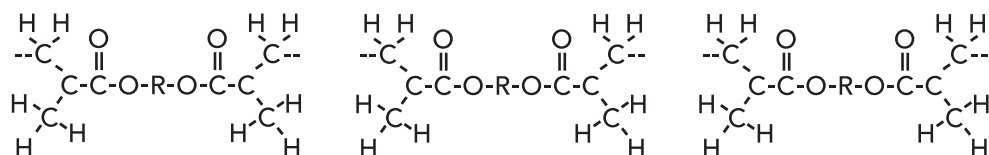


Figure 3c. Dimethacrylate monomers polymerize, resulting in polymerization shrinkage.

5.3 Reducing Polymerization Shrinkage

Polymerization shrinkage is influenced by clinical technique and manufacturing of the composite resin. There are several ways to reduce shrinkage from a manufacturing perspective, as described below.

Increase Filler Loading

Increasing filler loading in the resin matrix reduces polymerization shrinkage by decreasing the proportion of monomer content, thereby reducing shrinkage (Fig. 4).

Adjust the Monomers

Monomers with a low molecular weight shrink more during polymerization than those with higher molecular weights. Methacrylate monomers are typically used in dental composite resins, mainly bis-GMA and UDMA, due to their favorable physical properties. TEGDMA is usually added to adjust the viscosity and to make the composite material easier to handle. TEGDMA has a lower molecular weight than bis-GMA and UDMA (Table 2). Using less TEGDMA decreases polymerization shrinkage (Fig. 5).

Table 2. Molecular weight of monomers typically used in dental composites.



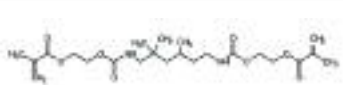
TEG DMA	Mw= 286.3	
Bis- GMA	Mw= 512.6	
UDMA	Mw= 470.6	

Figure 4. Influence of filler loading on shrinkage.

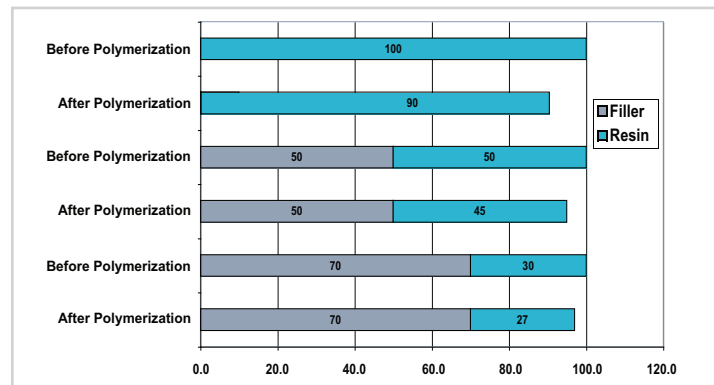
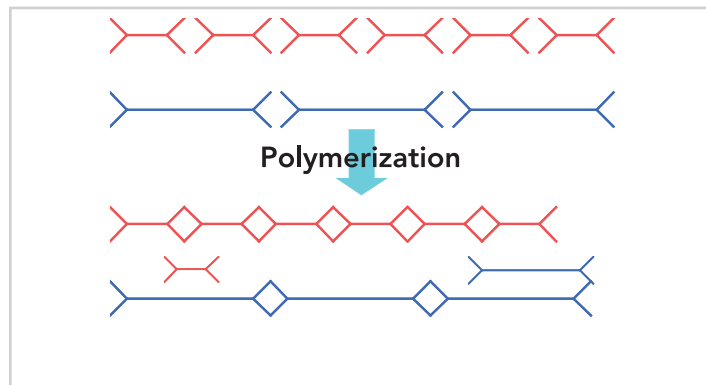


Figure 5. Polymerization shrinkage of low vs. high molecular weight monomers.



Use of Pre-polymerized Fillers

Pre-polymerized fillers are relatively large fillers with less surface area, enabling greater volumetric filler loading and thereby resulting in less volumetric shrinkage (Fig. 6b). These larger fillers also prevent the resin matrix from moving as a result of friction between the resin and the pre-polymerized filler surface during curing, thereby reducing shrinkage. This technology is used in GRADIA DIRECT.

Figure 6a. Shrinkage of microhybrid composites. The distance between the glass particles lessens during shrinkage.

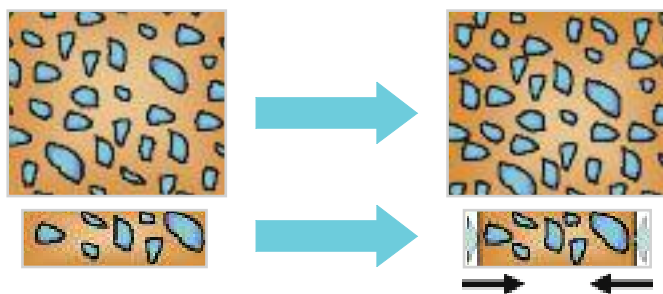
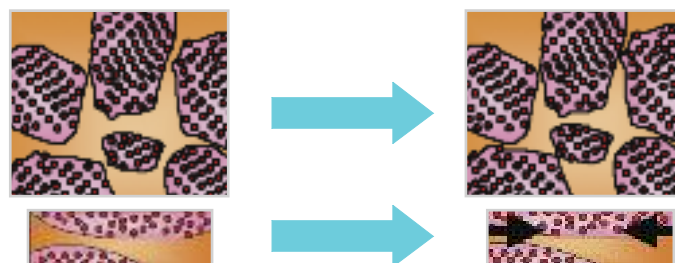


Figure 6b. Polymerization shrinkage of composites containing pre-polymerized fillers. Close contact between the pre-polymerized fillers prevents resin shrinkage.



5.4 Reducing Polymerization Shrinkage Stress

Polymerization shrinkage stress is the force generated at polymerization. During polymerization, the bonded composite resin will pull towards the cavity walls as shrinkage occurs. This force is shrinkage stress. At a given level of shrinkage, the most rigid materials result in the highest stress. The modulus of elasticity (Young's modulus) measures the rigidity of a material (its ability to resist deformation). The higher the modulus of elasticity, the greater the stress. There are several ways to reduce shrinkage stress, including the following:

Reduce Volumetric Shrinkage

Shrinkage stress can be decreased by reducing volumetric shrinkage, since the greater the volumetric shrinkage, the greater the force to pull the preparation wall.

Decrease the Modulus of Elasticity

Materials with a high modulus of elasticity result in stress build-up at the composite/tooth interface during polymerization shrinkage. In addition, brittle materials with a high modulus of elasticity are inefficient buffers for masticatory pressure. In contrast, materials with a low modulus of elasticity will deform and expand and, consequently, reduce stress at the composite/tooth interface (Fig. 7).

Increase the Initial Flow of the Material

If the composite resin is flowable, shrinkage will occur at the free surface and lead to a reduction in shrinkage stress at the composite/tooth interface (Fig. 7).

Figure 7a. Flowable and low modulus composites deform during polymerization. Shrinkage stress occurs at the free surface; consequently, less shrinkage stress occurs at the cavity walls.



Figure 7b. Composites with a high modulus of elasticity. These can only deform slightly during polymerization. Shrinkage stress will occur at the free surface and at the composite/tooth interface.



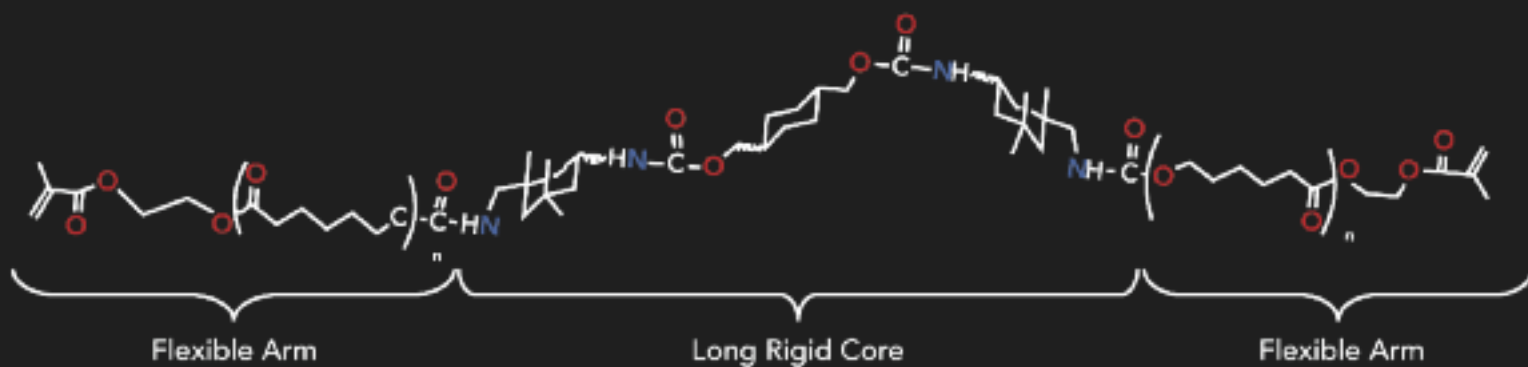
5.5 GC Corporation's Technology for Reduction of Shrinkage (Stress)

The new monomer DX-511, licensed from DuPont under an exclusive partnership agreement, is based on urethane dimethacrylate chemistry and designed to combine excellent handling and physical properties with low shrinkage (stress). DX-511 is compatible with all current composite and bonding systems.

DX-511 Monomer

The molecular structure of DX-511 includes a long rigid core and flexible reaction arms. The long rigid core retains its shape and size thereby overcoming the reduced capacity of flexible arms not to fold and lose volume, which prevents monomer deformation and reduces shrinkage. The flexible arms increase reactivity, overcoming the reduced reactivity usually associated with long monomer chains (Fig. 8). The molecular weight of DX-511 (Mw 895) is twice the molecular weight of bis-GMA or UDMA, reducing polymerization shrinkage since a smaller number of carbon double bonds (C=C) are present.

Figure 8. DX-511 Monomer.



Filler System

The HDR filler content of 30% wt. is optimized to reduce shrinkage, while still allowing easy shaping and manipulation of the material.

6.0 LABORATORY TESTING

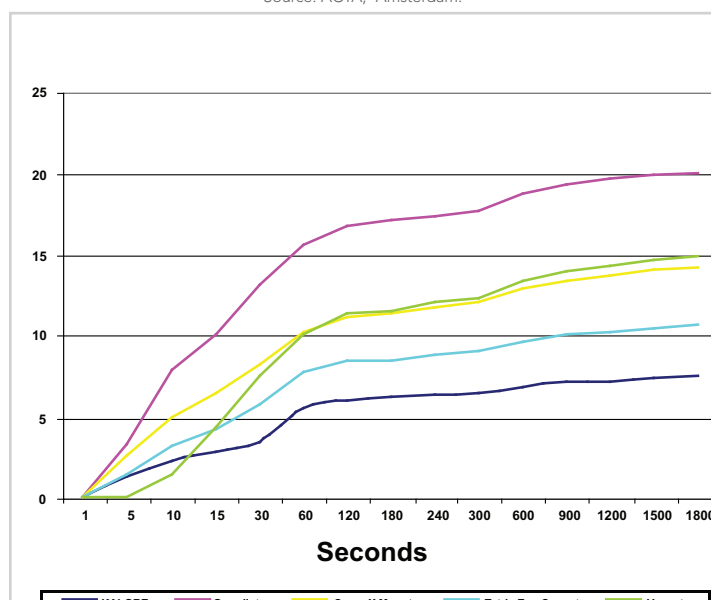
Laboratory testing was conducted externally as well as in-house at GC Corporation. To first test the hypothesis that the addition of the DX-511 monomer would result in improved properties of the composite, testing was conducted comparing two sets of composite samples that were identical except that one of the two groups had the addition of DX-511 monomer (KALORE). Specifically, comparisons were made for shrinkage stress, three-body wear resistance and combined polish retention/surface roughness. For the results of this testing, which confirmed the superiority of KALORE containing the DX-511 monomer over the composite without the DX-511 monomer, please refer to the document in the addendum. Extensive laboratory tests were also conducted comparing KALORE with other contemporary composites.

6.1 Shrinkage

Independent Testing - ACTA

Independent testing of volumetric setting shrinkage was conducted for several composites at the ACTA, Amsterdam. Measurements were continuously recorded using a mercury dilatometer. To conduct the test, composite was applied to the bottom surface of a glass stopper, which was then inserted into the mercury dilatometer. The sample was light-cured through the glass for 40 seconds with an Elipar[†] Highlight (750 mW/cm²). A computer was used to follow the shrinkage for a period of 4 hours or more at 23°C. To calculate the volumetric shrinkage, density measurements were performed after each shrinkage measurement using a Mettler Toledo AT 261 Delta Range[†] (Mettler Instruments AG). **Volumetric shrinkage was lowest for KALORE (Fig. 9).**

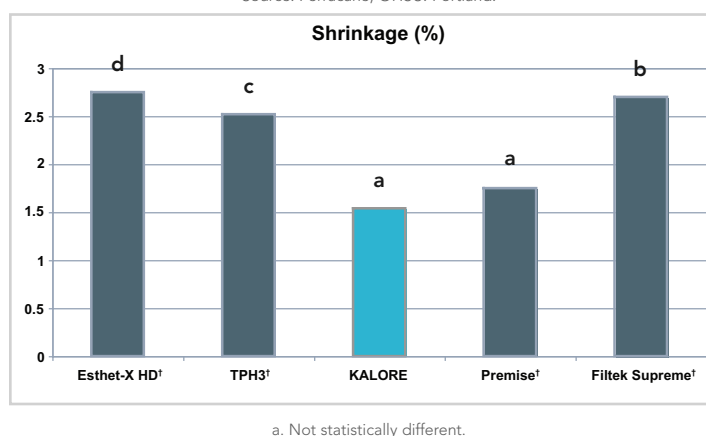
Figure 9. Volumetric shrinkage of various composite materials versus time.
Source: ACTA, Amsterdam.



Independent Testing - OHSU

Independent testing of volumetric shrinkage was also conducted by Dr. Jack Ferracane, in the Division of Biomaterials at OHSU School of Dentistry in Portland, OR. Volumetric shrinkage (VS) for three composites was determined in a mercury dilatometer. Composite samples weighing 150 mg were placed on glass slides that had been sandblasted with aluminum oxide (150 μ m particles) and coated with a silane coupling agent. The glass slide was clamped to the dilatometer column, on top of which a linear variable differential transducer (LVDT) was placed in contact with the surface of the mercury. The composite was photoactivated through the glass slide for 60 seconds at approximately 350-400 mW/cm². LVDT readings were recorded for 60 minutes at room temperature and correlated to volumetric shrinkage, based on data on composite mass and density that had been determined by the Archimedes method. The thermal expansion produced by the heat generated from the curing light was subtracted from the results by photoactivating for another 30 seconds after 60 minutes of data acquisition, and following the volumetric change for 30 minutes. The specimens were considered "fully" cured, i.e., cured with sufficient energy to maximize polymerization. Statistical testing of the data (ANOVA/Tukey's test) was performed to compare the three composites ($p < 0.05$). **Significantly less polymerization shrinkage was found with KALORE and Premise[†] compared to other composites (Fig. 10).**

Figure 10. Volumetric Shrinkage.
Source: Ferracane, OHSU, Portland.



Independent Testing - Indiana University

Independent testing of volumetric shrinkage on the same types of composites was conducted at a third site by Dr. Jeffrey A. Platt in the Division of Dental Materials, Indiana University School of Dentistry. Approximately 20 quarts of distilled water were poured into a Styrofoam container and allowed to stand overnight. The next day, the water temperature was recorded and checked periodically during the day for temperature stability. A density bottle was filled with water from the container and a stopper inserted (taking care to avoid the incorporation of any air bubbles into the vessel). The filled bottle was wiped dry and its weight recorded to the nearest 0.0001 gram. This procedure was repeated four times to obtain the average weight (used in the calculations for the value "B"). To obtain value "C", the bottle was filled approximately one-half full with distilled water, and approximately one gram of unpolymerized material was added. The bottle was then completely filled, weighed as above, and the average of three weight measurements used to determine the value for "C". The unpolymerized sample weights were recorded as a mean of three weights and used as value "D" (n=3).

Unpolymerized material was placed between two pieces of polyester film and squeezed to a thickness of about 1.5-2.0 mm. These samples were cured from both sides for 30 seconds each (for a total cure time of one minute). The cured samples were introduced to the density bottle in the same manner as previously described for the unpolymerized samples. Mean weights were used in the calculations for value "E". The samples were weighed before placing in the bottles and the mean of three measurements used as value "F" (n=3). Specimens were stored in sealed vials and measurements made immediately post-polymerization, after one day and after seven days. The volumetric polymerization shrinkage was obtained using equations:

Unpolymerized sample:	$U = (B - C + D) / D \text{ g/cm}^3$
Polymerized sample:	$P = (B - E + F) / F \text{ g/cm}^3$
Polymerization shrinkage	$PS = (1 - P / U) \times 100$

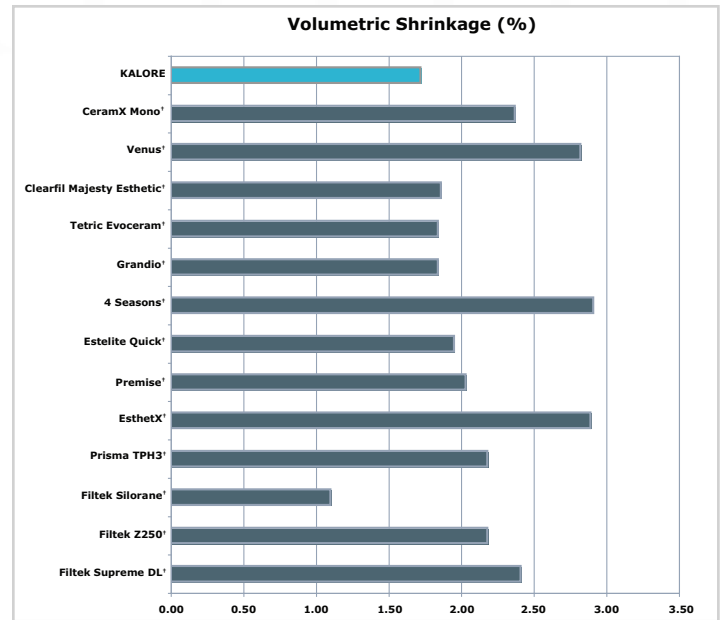
The data for each time period (initial, 1 day and 7 days) were each subjected to one-way ANOVA tests. **It was found that KALORE demonstrated significantly less volumetric polymerization shrinkage than all other composites tested at all time periods (Table 3).**

Table 3. Volumetric Polymerization Shrinkage.
All superscript letters indicate statistically similar groups, p<0.01 for all groups.

VPS (%)			
	Initial	One Day	Seven Days
KALORE	0.92 ± 0.21 ^a	0.55 ± 0.29 ^a	1.15 ± 0.23 ^a
Filtek Supreme Plus [†]	2.82 ± 0.19 ^c	2.05 ± 0.23 ^c	2.52 ± 0.12 ^b
EsthetX HD [†]	2.71 ± 0.34 ^c	2.45 ± 0.56 ^c	2.20 ± 0.29 ^b
Premise [†]	1.87 ± 0.30 ^b	1.20 ± 0.26 ^b	2.14 ± 0.27 ^b
TPH3 [†]	3.48 ± 0.24 ^d	3.10 ± 0.29 ^d	2.99 ± 0.36 ^c

Setting shrinkage was measured in-house, in accordance with ISO Draft 2007-07-10 Dentistry - Polymerization shrinkage of filling materials. Pre- and post-curing composite resin densities were measured and the polymerization shrinkage calculated accordingly. **KALORE demonstrated one of the lowest levels of volumetric shrinkage of all composites tested (Fig. 11).**

Figure 11. Volumetric shrinkage of various composite materials.
Source: GC Corporation.

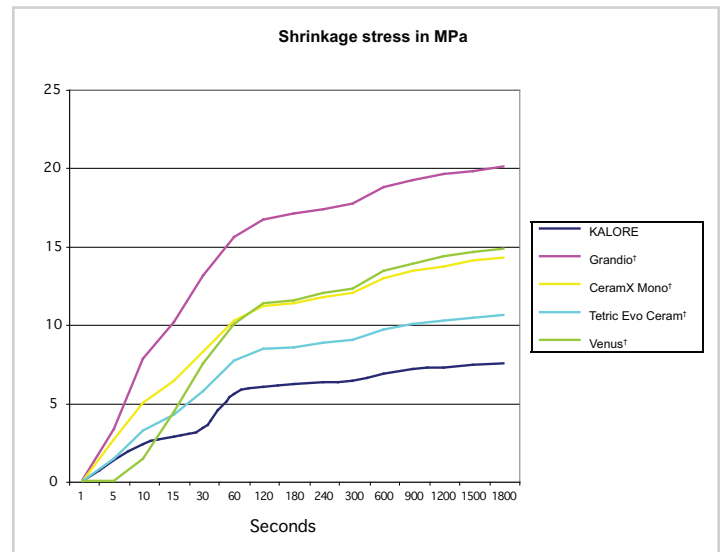


6.2 Shrinkage Stress

Independent Testing - ACTA

Independent testing of setting shrinkage stress using a tensiometer was conducted at the ACTA, Amsterdam. The composite material was inserted in a cylindrical shape between a glass plate and a parallel flat surface metal bolt head that was connected to a load-cell (the moving part). Using the tensiometer test, contraction stress values vary with the ratio of bonded to free surface area, known as the configuration factor or C-factor. A C-factor of 2 was used in the experiments. The contraction stress values represent the force required to combat the axial shrinkage of the composite and maintain the initial distance between the parts. The materials were light-cured for 40 seconds with an Elipar[†] Highlight in standard mode (750 mW/cm²). Shrinkage stress was measured for 30 minutes, while counteracting the axial contraction of the samples continuously by using a feedback displacement of the crosshead to keep the thickness of the sample constant at 0.8 mm. This simulated a restoration in a fully-rigid situation where the cavity walls cannot yield to contraction forces. **KALORE demonstrated the least shrinkage stress (Fig. 12).**

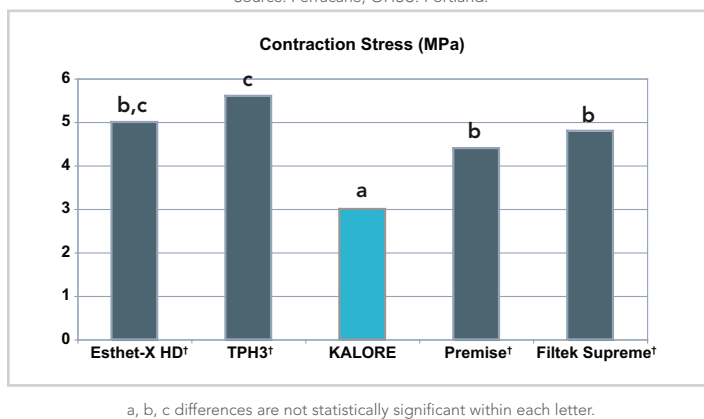
Figure 12. Shrinkage stress of various composite materials versus time.
Source: ACTA, Amsterdam.



Independent Testing of Shrinkage Stress - OHSU

Independent testing of shrinkage stress using a Bioman stress measurement device was conducted by Dr. Ferracane at OHSU School of Dentistry. This test uses a cantilever load-cell (500 kg) fitted with a rigid integral clamp, with a circular steel rod (10 mm diameter x 22 mm long) held vertically and perpendicular to the load-cell axis by the end of the cantilever. A removable, horizontal glass plate was placed underneath the rod and held rigidly in position by a Bioman clamp during testing. The lower end of the steel rod was sand-blasted, and the surface of the glass plate was silanated (but not sandblasted). An uncured composite sample 5 mm in diameter and 0.8 mm in thickness (representing a bonded to non-bonded surface area (C-factor) of ~3) was then introduced between the glass plate and the vertical rod to form an uncured specimen-disk. The composite sample was then light-cured from below for 40 seconds at 800 mW/cm². The load-signal from the cantilever cell was amplified and the signal was acquired by a standard computer. The registered load (in Newton, N) was then divided by the disk area in order to obtain the stress values (MPa). Subsequently, as in other studies using this methodology, the raw stress data were treated by a "correction factor" of four in order to relate the data to a low compliance system (such as a human tooth cusp). Measurements were performed for five minutes after curing. Testing was performed in this manner for five samples of each composite tested. After each evaluation, the Bioman clamps were removed and the set resin sample/glass-plate/metal piston was removed and carefully examined for any signs of debonding. If debonding occurred (which was rare), the debonded sample was excluded from the test results. Data was analyzed by the ANOVA/Tukey's test to compare the composites ($p < 0.05$). **It was found that the polymerization contraction stress of KALORE was significantly lower than for all other composites tested (Fig. 13).**

Figure 13. Contraction stress of tested composites.
Source: Ferracane, OHSU, Portland.



Independent Testing – Indiana University School of Dentistry

Independent testing of shrinkage stress was also conducted by Dr. Platt at Indiana University School of Dentistry. A tensometer was used to measure polymerization contraction stress. The tensometer consists of a rectangular beam (10 mm in width and 40 mm in height) made of stainless steel with a Young's modulus of 193 GPa that is clamped horizontally on the beam holder. During testing, the tensile force generated by the bonded shrinking composite sample deflects the cantilever beam. This deflection is measured with a linear variable differential transformer (LVDT), and the contraction stress is obtained by dividing the measured tensile force by the cross-sectional area of the sample. To perform the test, a composite sample was placed between two quartz rods positioned vertically in the tensometer. The top rod was connected to the cantilever beam at a distance of 12.50 cm from the beam holder, and the bottom quartz rod was used to complete the assembly to the tensometer and to guide the light from the curing unit to the sample. The LVDT was positioned 23 cm from the sample assembly at the free end of the cantilever beam.

Before each stress measurement, two pieces of quartz rod (6 mm in diameter) were flattened and polished with 600 grit wet silicon carbide paper, and two layers of silanation were applied to one end of each rod. The upper rod was mounted with the silanated end pointing down. Then the bottom quartz rod was aligned vertically to the upper rod and mounted with the silanated end pointing up. The distance between the two silanated ends was fixed at 2.25 mm for all samples. Thus, each composite sample was a disk 6 mm in diameter and 2.25 mm in height corresponding to a C-factor of 1.33 (diameter/2x height). A polytetrafluorethylene (PTFE) sleeve was placed around the gap between the two rods to keep the composite sample in place. Two holes were created on opposite sides of the sleeve, with the first hole (1.5 mm in diameter) used to inject the composite and the second one (0.5 mm in diameter) used as a vent during sample injection.

Under ambient yellow light, composite was injected into the sample holder to fill the space between the silanated ends (n=5). The composite was light-cured for 60 seconds through the bottom quartz rod with an Elipar[†] Highlight curing unit. The light intensity at the end of the quartz rods was measured at >600 mW/cm² and were checked between groups. If the intensity had changed, the lamp was replaced. Polymerization contraction stress kinetics was measured every second for 30 minutes from the initiation of light-curing. Contraction stress was determined by dividing the measured tensile force by the cross-sectional area of the sample. Maximum stress rates were determined by taking the first derivative of the stress vs. time curve. The gel point was identified as the first data point with a significant non-zero slope. The data was analyzed statistically using the one-way ANOVA test.

It was found that both the contraction stress and the maximum stress rate were lower for KALORE than for all other composites tested (Table 4). **The measured levels of stress should enhance the ability of KALORE to form intact dental adhesive interfaces. Furthermore, the lower rate of acquiring the contraction stress should also contribute to an improved stress environment for the interface.**

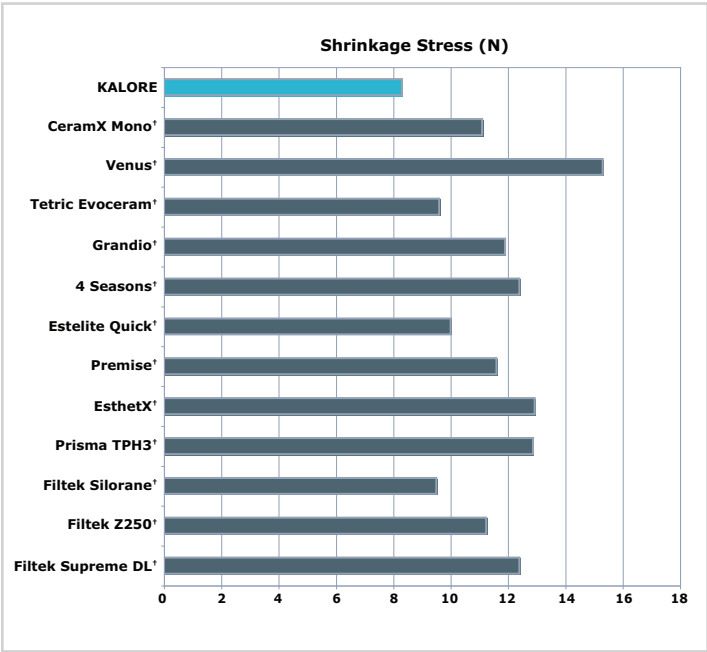
Table 4. Contraction stress, maximum stress rate and gel point.

	Contraction Stress (MPa)	Max Stress Rate (MPa/Min)	Gel Point (Mins)
KALORE	1.72 ± 0.10 ^a	2.80 ± 0.71 ^a	0.13 ± 0.02 ^a
Filtek Supreme Plus [†]	2.61 ± 0.26 ^b	5.62 ± 0.99 ^{b,c}	0.13 ± 0.01 ^a
EsthetX HD [†]	3.10 ± 0.13 ^c	6.62 ± 0.42 ^{c,d}	0.10 ± 0.13 ^a
Premise [†]	2.39 ± 0.17 ^b	7.48 ± 0.71 ^d	0.10 ± 0.13 ^a
TPH3 [†]	3.07 ± 0.15 ^c	9.08 ± 1.11 ^e	0.12 ± 0.01 ^a

All superscript letters indicate statistically similar groups (p<0.001 for contraction stress and p<0.01 for all other groups).

Setting shrinkage stress was measured in-house using a universal testing machine EZ-S (Shimadzu) with a custom-made jig. Two glass slides were pre-treated with sandblasting and a silane coupling agent, then attached to both the upper and the lower jig. A composite resin sample (1.66 mL) was placed on the lower glass slide and pressed by lowering the upper glass slide on it until a 4 mm clearance remained between the upper and lower glass slides (Fig. 15).

Figure 14. Shrinkage stress of various composite materials.
Source: GC Corporation.



The sample was light-cured for 40 seconds from the underside using a G-Light™ 11 mm fiber rod, then light-cured for 20 seconds from above. The setting shrinkage stress was measured for 20 minutes and the highest figure reached was recorded as the shrinkage stress. **KALORE demonstrated the lowest shrinkage stress of all products tested (Fig. 14).**

Figure 15. Universal testing machine EZ-S (Shimadzu) with custom-made jig.

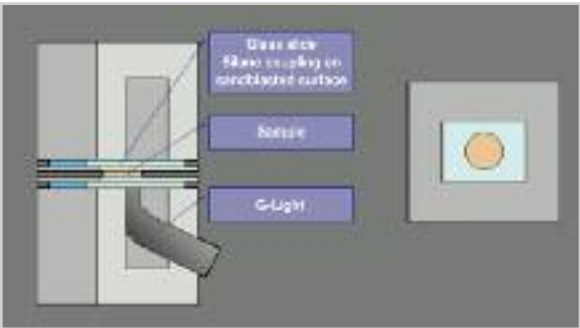
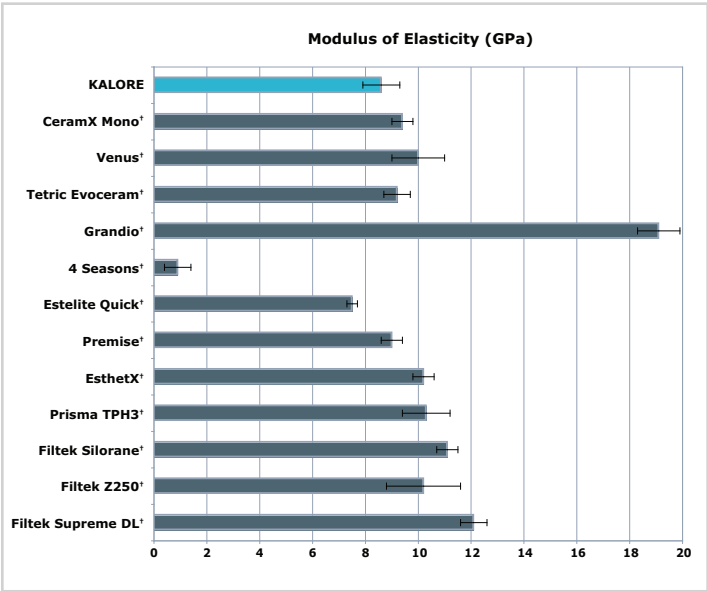


Figure 16. Modulus of elasticity of various materials.
Source: GC Corporation.



6.3 Modulus of Elasticity

The modulus of elasticity (Young's modulus), a measure of the rigidity of the material, is defined by the initial slope of a stress-strain curve. A material with a high modulus is stiff and rigid, whereas a material with a low modulus is flexible. Ideally, a material should not have too high a modulus of elasticity as brittle materials are less able to buffer masticatory pressure. The modulus of elasticity for KALORE was determined in accordance with ISO 4049 specifications for flexural strength measurements. **KALORE behaved like a rigid material, yet was elastic enough to buffer masticatory pressure (Fig. 16).**

6.4 Fracture Toughness

Fracture toughness, a measure of a material's ability to resist the propagation of a formed crack, is defined as the toughness against bending stress. The toughness is calculated as the underlying area of a stress-strain curve. A higher value for fracture toughness implies greater resistance to the catastrophic propagation of cracks. **KALORE demonstrated high resistance to crack propagation (Fig. 17).**

Independent Testing - OHSU

Independent testing of fracture toughness was conducted by Dr. Ferracane at OHSU School of Dentistry in accordance with ASTM E399. Samples (2.5 mm x 5 mm x 25 mm) were made in stainless steel molds, and a razor blade notch was created at the mid-span with an a/w of 0.5 (where a = the length of the notch and w = the sample height). Specimens were light-cured for 40 seconds from the top and bottom in the Triad II⁺ unit. The samples were stored in water at 37°C for 24 hours and then tested for three-point bending (20 mm span) on a universal testing machine at a cross-head speed of 0.254 mm/minute. The fracture toughness was determined using the maximum load (there was no evidence of plastic deformation). Data was analyzed by the ANOVA/Tukey's test to compare the composites ($p < 0.05$). The fracture toughness of all composites was found to be the same, except for TPH3 (Fig. 18).

Figure 17. Fracture toughness of various composite materials.
Source: GC Corporation.

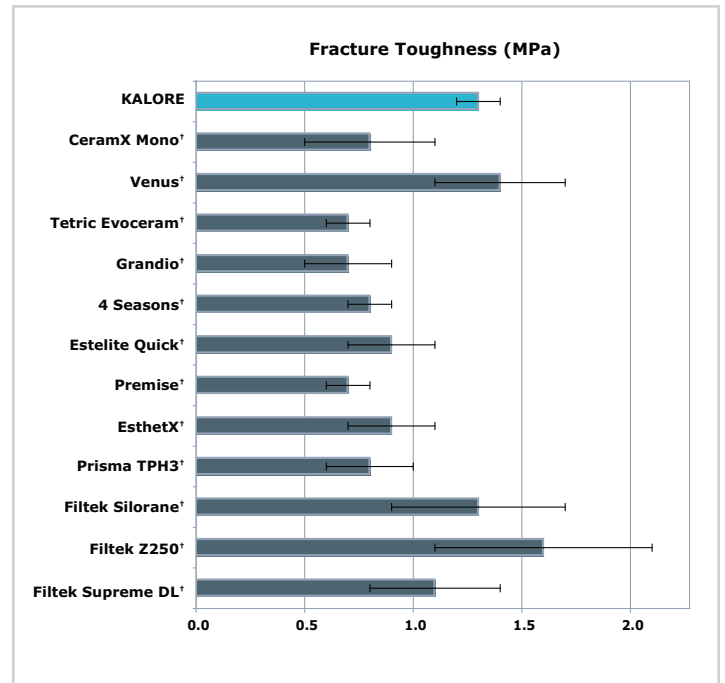


Figure 18. Fracture toughness.
Source: Ferracane, OHSU. Portland.

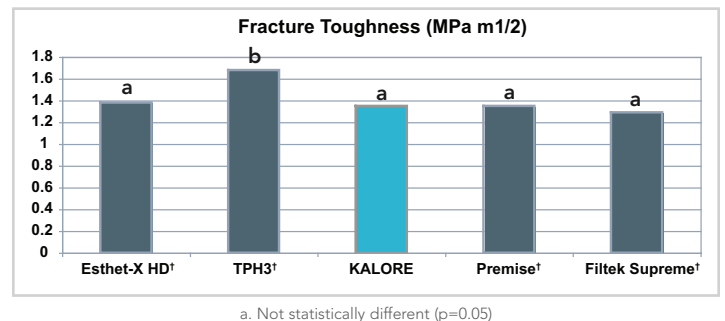
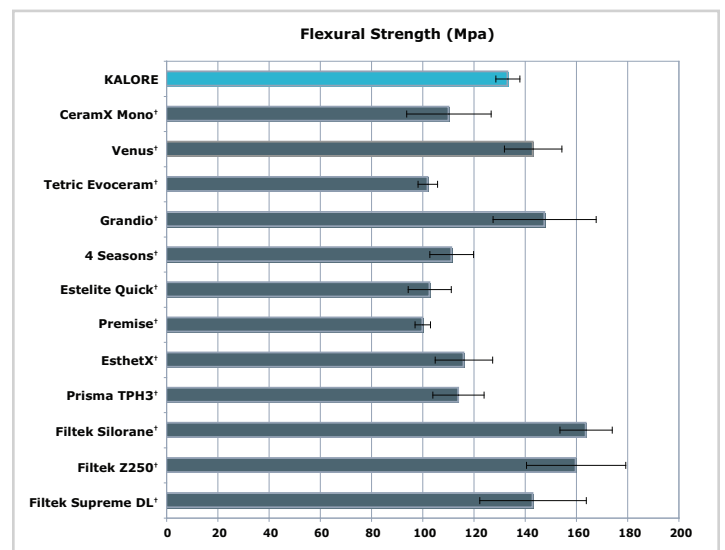


Figure 19. Flexural strength of various composite materials.
Source: GC Corporation.

6.5 Flexural Strength

The flexural strength was measured in accordance with ISO4049:2000. **KALORE demonstrated high flexural strength (Fig. 19).**



6.6 Three-Body Wear Resistance

To measure three-body wear resistance in-house, composite specimens were prepared and moved up and down along a 5 cm path at a rate of 30 strokes per minute. They were held in indirect contact with an acrylic plate under a load of 350 gf and, simultaneously, the sample holder slid horizontally along a 2 cm path at a rate of 30 strokes per minute. A mixture of PMMA and glycerol (1:1 volume) was used as an intermediate abrasive (Fig. 20). After 100,000 cycles (with one complete lateral and vertical movement being defined as one cycle), material wear was evaluated by measuring height loss. **KALORE was found to have high resistance to three-body wear (Fig. 21).**

Following this test, samples of composites were processed for SEM imaging. **KALORE was found to have durable and tight bonding between the fillers and the resin matrix. In the same test, other products demonstrated defects at the pre-polymerized filler interface (EvoCeram[†]) or at the interface with the glass particle (Grandio[†] and TPH3[†]).** In addition, filler dropouts were observed (Fig. 22).

Figure 20. Three-body wear resistance test set-up.

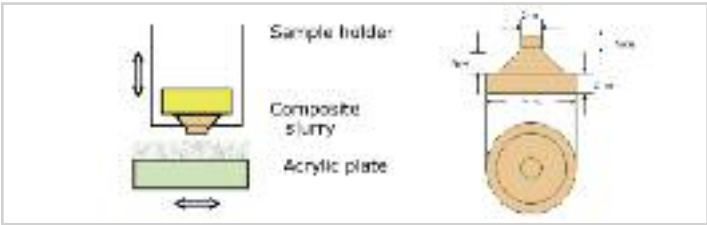


Figure 21. Three-body wear of various composite materials. Source: GC Corporation.

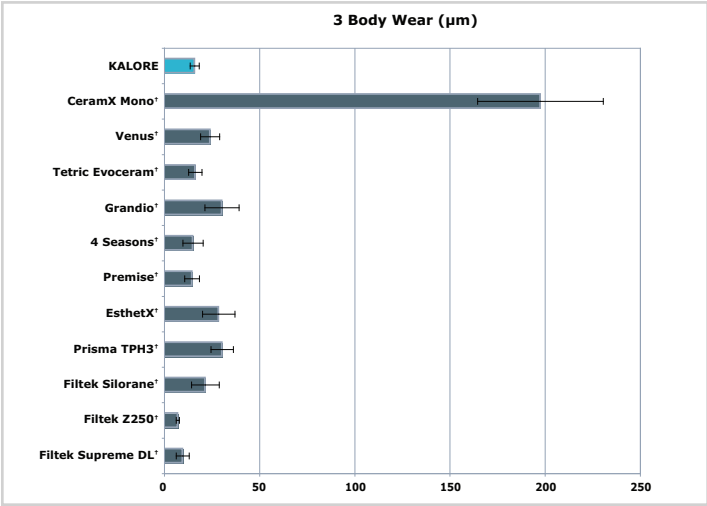
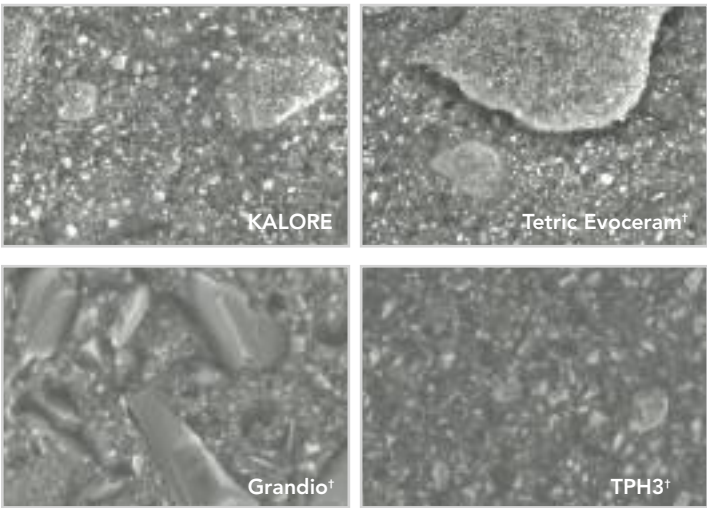


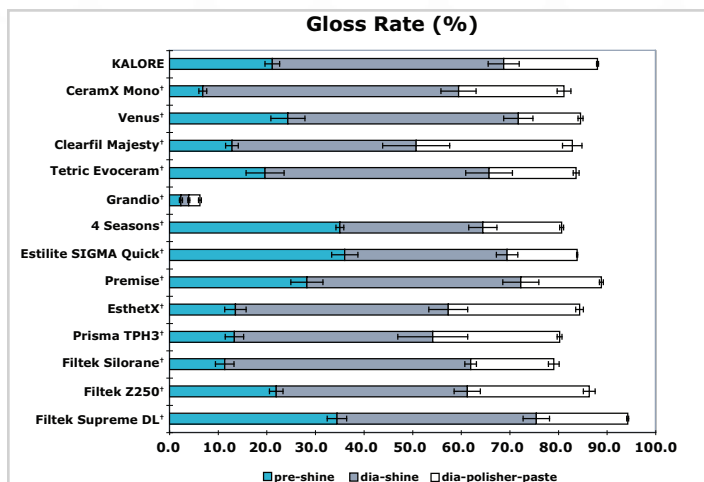
Figure 22. SEM images of samples tested for three-body wear resistance (x5000).



6.7 Surface Gloss

To test surface gloss, samples 15 mm in diameter and 1.5 mm thick were light-cured and finished with 600 grit sandpaper. Finished samples were polished in steps with GC Pre-Shine, GC Dia-Shine and GC Dia Polisher paste. After each polishing step, the surface gloss rate was measured using a VG-2000[†] (Nippon Denshoku). **KALORE** was found to have a gloss rate among the highest of all materials tested (Fig. 23).

Figure 23. Surface gloss of various composite materials.
Source: GC Corporation.

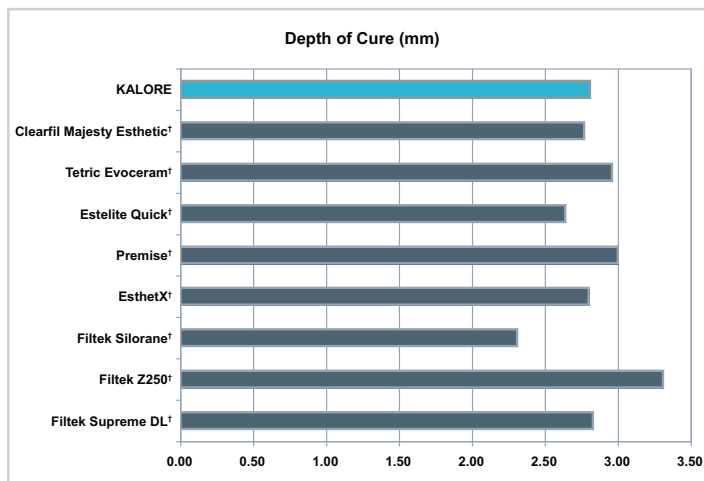


Note: A 50% gloss rate represents a shiny surface whereas a figure of 70% and higher shows an aesthetically pleasing shiny surface.

6.8 Depth of Cure

The depth of cure of KALORE shade A2 was tested using a scraping technique and found to be 2.81 mm, **sufficient to guarantee a good cure (Fig. 24).**

Figure 24. Depth of cure for KALORE.
Source: GC Corporation.



6.9 Radiopacity

The radiopacity of KALORE was measured in accordance with ISO4049:2000. The ADA Professional Product Review states that the radiopacity of enamel and dentin are 225%AI and 150%AI respectively (Fig. 25a). **The radiopacity of KALORE was found to be greater than 2.5 mm AI (Fig. 25b).**

Figure 25a. KALORE Radiopacity.
Source: GC Corporation.

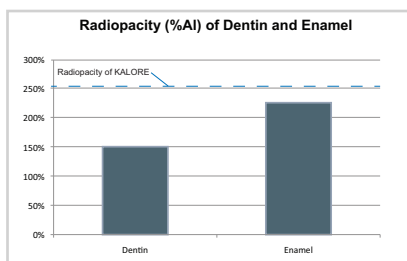
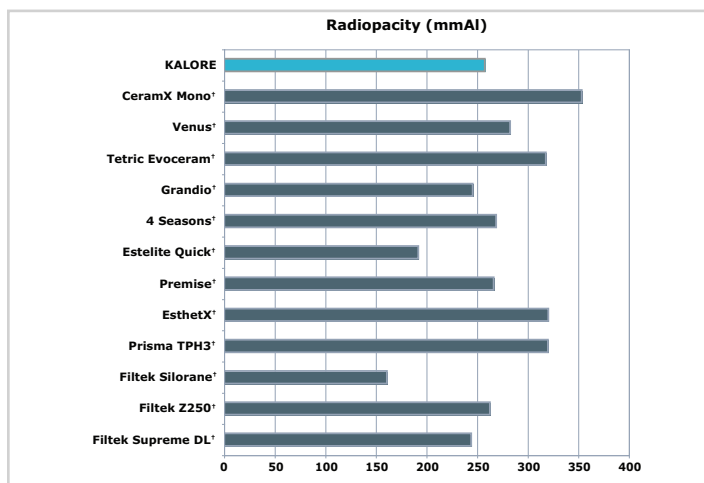


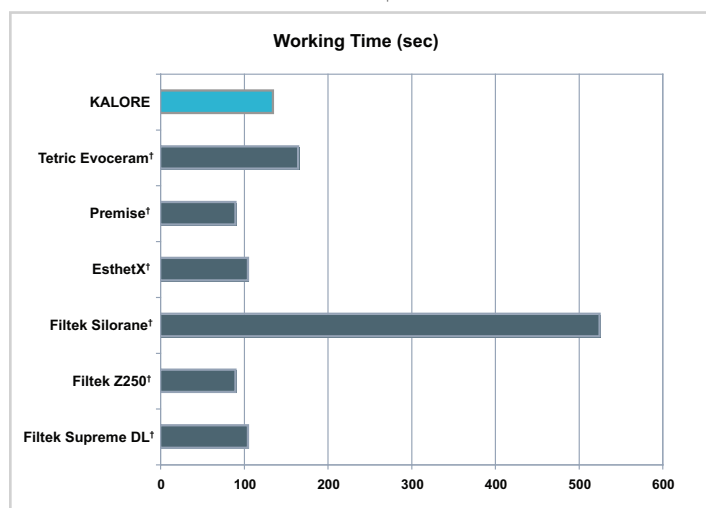
Figure 25b. Radiopacity of various composite materials.
Source: GC Corporation.



6.10 Handling and Working Time

The working time of various composite materials was tested. **The working time for KALORE was found to be sufficient, at 135 seconds (Fig. 26).**

Figure 26. Working time of various composite materials.
Source: GC Corporation.



7.0 SHADES AND AESTHETICS

Reproducing well-balanced color harmony is one of the greatest challenges in prosthetic and restorative dentistry. Patients demand aesthetic restorations that are indistinguishable from the natural tooth structure, and preferably that also improve on nature. KALORE offers predictable aesthetics for all direct restorations and makes it possible to balance dental science and the artistry of a patient's smile in all clinical direct restorative cases.

KALORE offers state-of-the-art shades for highly aesthetic restorations. The shades have been designed to mimic the translucency, opalescence, hue (pure color), chroma (color saturation), value (lightness or darkness of color) and fluorescence of natural teeth. The opalescence produces shimmering pale colors (similar to opals), while the fluorescence determines the ability to absorb UV light and emit visible (mostly bluish) light. The level of translucency determines the transmission of light through the tooth or material. The value helps determine how life-like a restoration will be upon completion (Fig. 27). If only hue and chroma are determined for the color of a restoration, the lack of value will result in a less life-like result. The enamel surface is the main contributor to value. The incisal and approximal areas of the tooth are good sites to determine the value of a tooth.

The chameleon effect of KALORE results in a composite restoration indistinguishable from the surrounding tooth structure. The reflected light from a composite restoration should be similar to the reflected light from the tooth structure. Composite materials must have a chameleon effect to be suitable for both simple and complex cases.

Figure 27. Influence of value on color perception.



7.1 Shade Ranges

The shades of KALORE are designed for single and multi-shade layering techniques.

KALORE has three clearly defined shade groups with clearly defined colors for easy recognition:

- Universal shades (color code on unitip cap / syringe label: green)
- Opaque shades (color code on unitip cap / syringe label: burgundy)
- Translucent shades (color code on unitip cap / syringe label: grey)

The universal shades are ideal for single-shade layering techniques. The opaque and translucent shades were developed to satisfy the need for high aesthetics. These shades can be used alone or together in combination for restorations, and can also be used with the universal shades.

7.2 Universal Shades

Universal shades have a very delicate balance between value, translucency, hue and chroma and were developed for a single-shade layering technique. They are grouped into A (reddish-brown), B (reddish-yellow), C (grey), D (reddish-grey), Bleach and Cervical shades. Each shade from the same group has the same hue with an increasing amount of chroma per group. These properties make the Universal shades ideal for single-shade layering techniques.

Table 5. Overview of KALORE universal shades.

Universal Shades				
XBW				
BW				
	A1	B1		
	A2	B2	C2	D2
	A3	B3	C3	
	A3.5			
	A4			
		CV (B5)		
		CVD (B7)		

Each shade from the same group conforms to the arrangement of the Vita[®] classical shade guide.

Examples of perfect shade matching include:

- KALORE shade A2 matches Vita[®] shades B1, A1 and B2.
- KALORE shade A3 matches Vita[®] shades D2, A2, C1, C2, D4, A3, B3, A3.5, and B4.
- KALORE shade CV matches Vita[®] C3, A4 and C4.

The chameleon effect can be seen by applying KALORE to the center of corresponding Vita® classical shade guide fingers (Fig. 28).

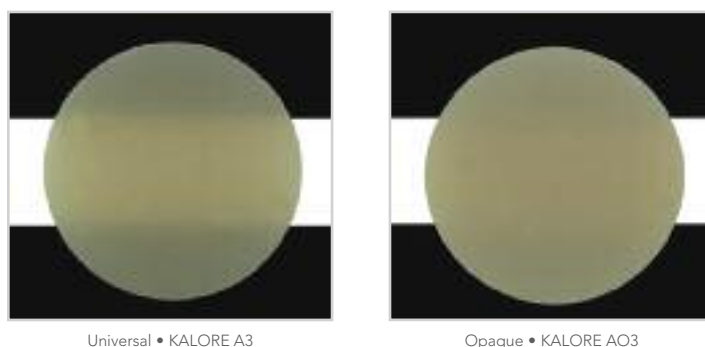
Figure 28. Chameleon effect of KALORE Universal shades applied to different Vita® shades.



7.3 Opaque Shades

KALORE Opaque shades are available as AO2, AO3, AO4, OBW and XOBW. Their increased opacity prevents light from the oral cavity being transmitted through the restoration, which would result in a darker appearance (Fig. 29).

Figure 29. Difference in opacity between Universal A3 and Opaque AO3.



7.4 Translucent Shades

The translucent shades provide the ability to give more “life” to the final restoration, and to mimic the value and age-dependent enamel changes. Due to the uniqueness of these shades a classification to Vita® is not possible and the KALORE shade guide should be used.

Translucent shades can be grouped in two levels of translucency:

- CT (clear translucent)
- NT (natural translucent), WT (white translucent), DT (dark translucent), GT (grey translucent) and CVT (cervical translucent)

The translucent shades give an extra dimension and vitality to restorations. As we age, the enamel changes in character from thick to thin, with an accompanying reduction in value (less white, more black) and the enamel becomes more translucent. Shading changes also occur, especially cervically. Special attention must be paid to these changes for aesthetic results. To provide age-appropriate values, different KALORE shades are available: WT (child) DT (adult) and GT (senior). To mimic the increase in translucency, for example at the incisal edges of teeth in adults and elderly patients, NT and CT shades are available (Fig. 30).

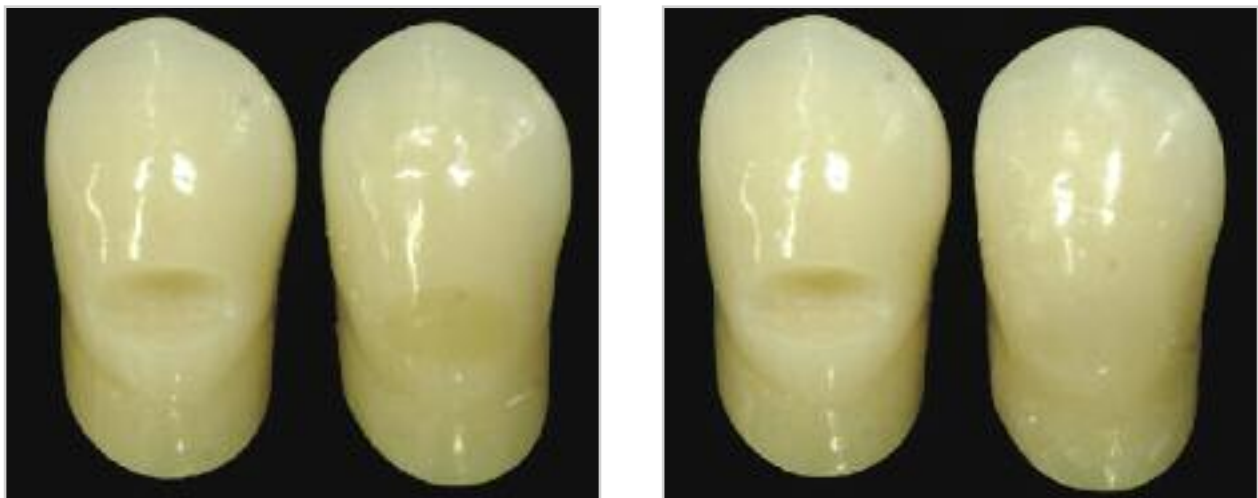
Figure 30. Class IV cavity restored with differing shades.



AO3, A3 and NT on left side, AO3 and A3 on right side.

The application of CVT will increase the vividness of Class V restorations significantly (Fig. 31).

Figure 31. Class V restorations with cervical shading.



CV on left side, CV and CT on right side.

7.5 Chameleon Properties

KALORE offers excellent chameleon properties due to the different interfaces within the material. These result in optical properties and light reflection that are similar to tooth structure (Fig. 32) and enable single and multi-shade restorations with unrivaled aesthetics (Fig. 33).

Figure 32a. Diffused reflection of KALORE compared to natural teeth and hybrid composites.

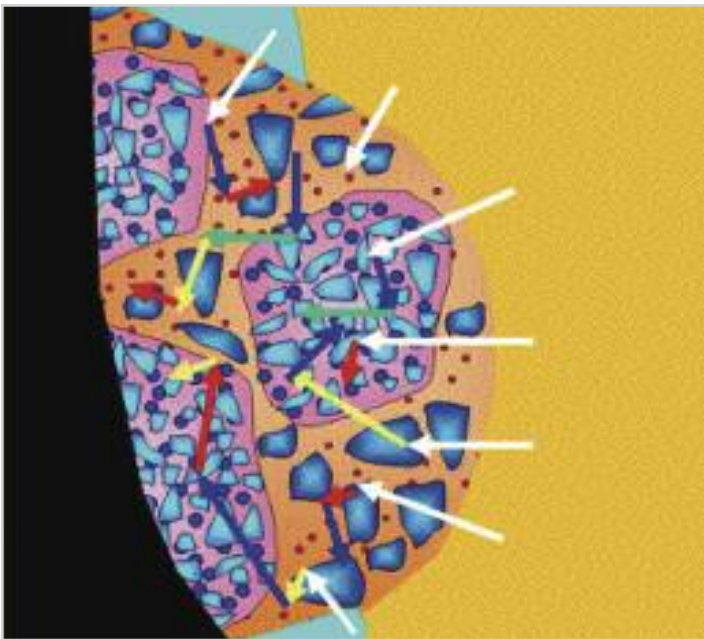


Figure 32b. Reflection of a natural tooth.

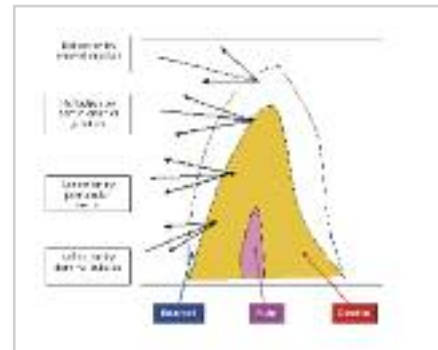


Figure 32c. Reflection and components of KALORE.

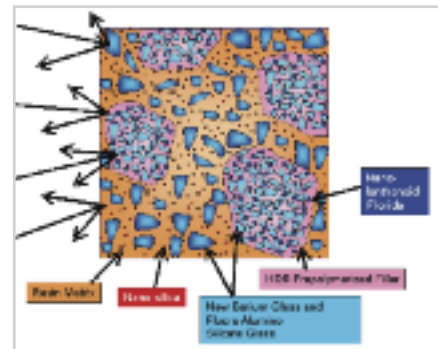


Figure 32d. Reflection in hybrid composites.

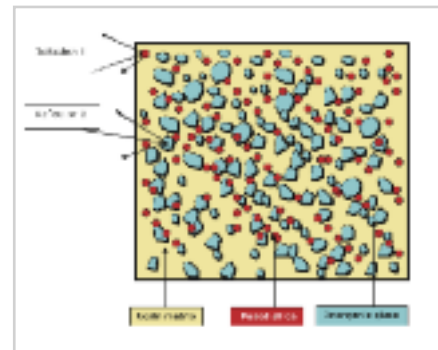


Figure 33. Class V restoration restored with only Universal A2.
Courtesy Dr. Wynn Okuda.



Note the excellent chameleon properties of KALORE.

7.6 Shade Guide

KALORE shades are linked to the Vita® Classical shade guide. For shade matching with KALORE, the body section is the most representative part of this guide. However, several translucent shades are custom made and require use of the KALORE shade guide. The individual shade samples increase in thickness to enable the clinician to judge the influence of thickness of the composite layer of each shade on the shade guide (Fig. 34).

Figure 34. KALORE shade guide.



7.7 Shade Selection for Existing and New Users

New Users of GC Composite Materials

In 90% of cases, a Universal shade will be sufficient.

In 10% of cases, a combination of Universal, Opaque and/or Translucent shades will be required for optimal aesthetics. Table 6 shows the combination of KALORE composite shades ("painting by numbers principle") that can be used for restorations, and Table 7 shows the age-related shades that can be used.

Table 6. Restoring with three or four shades.

# Shades	A1	A2	A3	A3.5	A4	B1	B2	B3	C2	C3	D2	CV	CVD	BW	XBW
1. Opaque	OBW	AO2	AO3	AO3	AO4	OBW	AO2	AO3	AO3	AO4	AO2	AO4	AO4	OBW	OXBW
2. Universal	A1	A2	A3	A3.5	A4	B1	B2	B3	C2	C3	D2	CV	CVD	BW	XBW
3. Translucent	WT	WT	DT	DT	DT	WT	WT	DT	DT	DT	WT	DT	DT	WT	WT
4. Incisal Edge	CT	NT	NT	NT	GT	CT	NT	NT	NT	GT	CT	CVT	CVT	CT	CT

Table 7. Restoring by age category.

	Junior	Adult	Senior
Translucent (Enamel)	WT	DT	GT
Translucent (Incisal Edge)	WT	NT	CT

Existing Users of GC Composite Materials

The tables below show the shade ranges available for the composite materials available through GC America.

Table 8a. Standard / universal shades.

	Standard / Universal Shades																				
	A1	A2	A3	A3.5	A4	A5	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4	BW	XBW	CV	CVD
VITA®†	X	X	X	X	X	-	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-
GRADIA DIRECT A	X	X	X	X	X	-	X	X	X	-	-	-	X	-	-	-	-	X	X	X	X
GRADIA DIRECT P	X	X	X	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
GRADIA DIRECT X	X	X	X	X	-	-	X	X	-	-	-	X	-	-	X	-	-	X	X	-	-
KALORE	X	X	X	X	X	-	X	X	X	-	-	X	X	-	X	-	-	X	X	X	X

Table 8b. Inside special / opaque shades.

	Inside Special / Opaque Shades																				
	OA1	OA2	OA3	OA3.5	OA4	OA5	OB1	OB2	OB3	OB4	OC1	OC2	OC3	OC4	OD2	OD3	OD4	OBW	OBXW	CV	CVD
VITA®	X	X	X	X	X	-	X	X	X	X	X	X	X	X	X	X	X	-	-	-	-
GRADIA DIRECT A	-	X	X	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
GRADIA DIRECT P	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
GRADIA DIRECT X	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
KALORE	-	X	X	-	X	-	-	-	-	-	-	-	-	-	-	-	-	X	X	-	-

Table 8c. Outside special / translucent shades.

	Outside Special / Translucent Shades						
	CT	NT	DT	WT	GT	CVT	AT
VITA®	-	-	-	-	-	-	-
GRADIA DIRECT A	X	X	X	X	X	X	-
GRADIA DIRECT P	-	X	-	X	-	-	-
GRADIA DIRECT X	-	-	-	X	-	-	-
KALORE	X	X	X	X	X	X	-

Main Differences Between GC KALORE and GRADIA DIRECT Shades

1. Changes in terminology:
 - Universal shades versus Standard shades
 - Opaque shades versus Inside special
 - Translucent shades versus Outside special
2. Changes in bleach shades:
 - KALORE shades OBW and OXBW are same as GRADIA DIRECT shades BW and XBW.
 - KALORE shades BW and XBW are new universal bleach shades with no equivalent GRADIA DIRECT shade.
3. Change in C2 and D2:
 - KALORE shades C2 and D2 have a translucency similar to the other Universal shades.
GRADIA DIRECT X shades C2 and D2 are more translucent.
4. Change in NT and CT:
 - KALORE shades CT and NT are slightly less translucent than CT and NT in GRADIA DIRECT shades.

8.0 CYTOTOXICITY DATA

KALORE was rigorously tested for toxicity of the new monomer (DX-511) using several tests based on ISO7405 and 10993. All test results were negative for toxicity (Table 9).

Table 9. Results of cytotoxicity tests with KALORE.

Test Item	Method	Result
Cytotoxicity test	Agar diffusion	Negative
Sensitization test	Maximization	Negative
Irritation or intracutaneous reactivity	Oral mucosa irritation	Negative
Subchronic systemic toxicity	ISO 10993-11 and ISO 10993-12	Negative
Genotoxicity	Ames, Mouse lymphoma	Negative
Local effects after implantation	1 month, 6 months	Negative

9.0 CLINICAL INVESTIGATIONS

Post-operative sensitivity and other clinical parameters of Class II made with KALORE resin composite after one year of clinical service

Ferrari M, Cagidiaco MC, Chazine M, Paragliola R, Grandini S. University of Siena, Italy.

Purpose: The aim of this clinical study was to evaluate the post-operative sensitivity and clinical performance of Class II restorations made with KALORE resin composite in combination with G-BOND™.

Materials and Methods: Patients were selected who required either one or two restorations. A total of 40 restorations were placed. Adhesive procedures were performed in accordance with the manufacturer’s instructions. Before applying the bonding material, pain was measured utilizing a simple response-based pain scale. Response was determined to a one-second application of air from a dental unit syringe (at 40-65 psi and approximately 20°C), directed perpendicular to the root surface at a distance of 2 cm as well as to tactile stimuli with a sharp #5 explorer. The restorations were placed by the same operator, while the clinical evaluations at recall visits were made by a second operator (double blind approach). The restorations were evaluated immediately following placement and at day 1 and day 7, then after 1 and 12 months for post-operative sensitivity, marginal discoloration, marginal integrity, secondary caries, maintenance of interproximal contacts and fractures. The other evaluated clinical parameters were vitality and retention.

Results: Three preparations showed moderate sensitivity at baseline before placing restorations (Table 10). Post-operative sensitivity progressively reduced over time and had completely disappeared by the 1-year recall. After one year, only two restorations presented with marginal discoloration (1 alpha, 1 beta score).

Conclusion: The combination of G-BOND and KALORE resulted in no post-operative sensitivity 1 year post-placement.

Table 10. Performance criteria according to Ryge. For post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity).

Criteria and number of restorations evaluated at 1-year recall		G-BOND and KALORE [n=40]			
		alpha	bravo	charlie	delta
Marginal discolorations and integrity	38	1	1	0	0
Secondary caries	40	0	0	0	0
Vitality test	40	0	0	0	0
Interproximal contacts	40	0	0	0	0
Retention	40	0	0	0	0
Fracture	40	0	0	0	0
Post-operative sensitivities		No	Yes	Mean	SD
	40	40	0	0	0

10.0 LITERATURE

- 1-year evaluation of Class II made with "KALORE" resin composite. M. Ferrari, M. Cagidiaco, M. Chazine, R. Paragliola and S. Grandini. EADR 2009, abstract 010.
- Polymerization Shrinkage Ratio and Force of Various Resin Composites. F. Fusejima, S. Kaga, T. Kumagai and T. Sakuma. EADR 2009, abstract 0292.
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- Achieving Excellence Using an Advanced Biomaterial, Part 1. Douglas A. Terry, Karl F. Leinfelder, Markus B. Blatz. Dentistry Today, August 2009.
- Creating Lifelike Aesthetics Using Direct Composites. Frank Milnar. Dentistry Today, August 2009.
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11.0 ORDERING INFORMATION

KALORE is available in 26 shades: 15 universal (color code on unitip cap / syringe label: green), 5 opaque (color code on unitip cap / syringe label: burgundy) and 6 translucent (color code on unitip cap / syringe label: grey).

Packages: Trial Kits: Unitip - A1(20), A2(20) & BW(10) (.3g/.16mL per tip). Syringe - 1 each: A1, A2 & BW. (4g/2.0mL per syringe).
Unitip Refills - 10 count & 20 count (.3g/.16mL per tip) & Syringe Refills - 1 count (4g/2.0mL per syringe).

Trial Kits		
Syringe SKU#	Unitip SKU#	Shades
003624	003569 (10 count)	A1, A2 & BW (Bleaching White)

Opaque Shade Refills		
Syringe SKU#	Unitip SKU#	Shade
003572	003598 (10 count)	AO2
003573	003599 (10 count)	AO3
003574	003600 (10 count)	AO4
003575	003601 (10 count)	OBW (Opaque Bleaching White)
003576	003602 (10 count)	OBW (Opaque Extra Bleaching White)

Translucent Shade Refills		
Syringe SKU#	Unitip SKU#	Shade
003592	003607 (10 count)	WT (White Translucent)
003593	003608 (10 count)	DT (Dark Translucent)
003594	003609 (10 count)	CT (Clear Translucent)
003595	003610 (10 count)	NT (Natural Translucent)
003596	003611 (10 count)	GT (Grey Translucent)
003597	003612 (10 count)	CVT (Cervical Translucent)

Universal Shade Refills		
Syringe SKU#	Unitip SKU#	Shade
003577	003613 (20 count)	A1
003578	003614 (20 count)	A2
003579	003615 (20 count)	A3
003580	003616 (20 count)	A3.5
003581	003617 (20 count)	A4
003582	003618 (20 count)	B1
003583	003619 (20 count)	B2
003584	003620 (20 count)	B3
003585	003621 (20 count)	C2
003586	003622 (20 count)	C3
003587	003623 (20 count)	D2
003588	003603 (10 count)	CV (B5: Cervical)
003589	003604 (10 count)	CVD (B7: Cervical Dark)
003590	003605 (10 count)	BW (Bleaching White)
003591	003606 (10 count)	XBW (Extra Bleaching White)

12.0 INSTRUCTIONS FOR USE

GC KALORE LIGHT-CURED RADIOPAQUE UNIVERSAL COMPOSITE RESTORATIVE

For use only by a dental professional in the recommended indications.

RECOMMENDED INDICATIONS

1. Direct restorative for Class I, II, III, IV, V cavities.
2. Direct restorative for wedge-shaped defects and root surface cavities.
3. Direct restorative for veneers and diastema closure.

CONTRAINDICATIONS

1. Pulp capping.
2. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

DIRECTIONS FOR USE

1. Shade Selection

Clean the tooth with pumice and water. Shade selection should be made prior to isolation. Select the appropriate shades by referring to the KALORE Shade Guide or Multi Shade Build-Up Guide.



2. Cavity Preparation

Prepare cavity using standard techniques. Dry by gently blowing with oil free air.

Note: For pulp capping, use calcium hydroxide.



3. Bonding Treatment

For bonding KALORE to enamel and / or dentin, use a light-cured bonding system such as GC Fuji BOND™ LC, UniFil® Bond or G-BOND™ (Fig. 1). Follow manufacturer's instructions.



4. Placement of KALORE

1) Dispensing from a Unitip

Insert the KALORE Unitip into a commercially available applicator. (Centrix Applicator is recommended.)

Refer to the applicator manufacturer's instructions for use. Remove the cap and extrude material directly into the prepared cavity. Use steady pressure (Fig. 2).

2) Dispensing from a syringe

Remove syringe cap and dispense material onto a mixing pad. Place the material into the cavity using a suitable placement instrument. After dispensing, screw syringe plunger anticlockwise by a half to full turn to release residual pressure inside the syringe. Replace cap immediately after use.

Note:

1. Material can be applied in a single shade layer to achieve aesthetic restorations using Universal shades. For details, refer to the Clinical Hints.
2. Material may be hard to extrude immediately after removing from cold storage. Prior to use, let stand for a few minutes at normal room temperature.
3. After dispensing, minimize exposure to ambient light. Ambient light can shorten the manipulation time.

CLINICAL HINTS

a. In the case of small cavities

Restore using a one shade technique. In most cases the use of one Universal shade alone will be sufficient. In cases where a higher degree of translucency is needed, one of the Translucent shades can be selected.

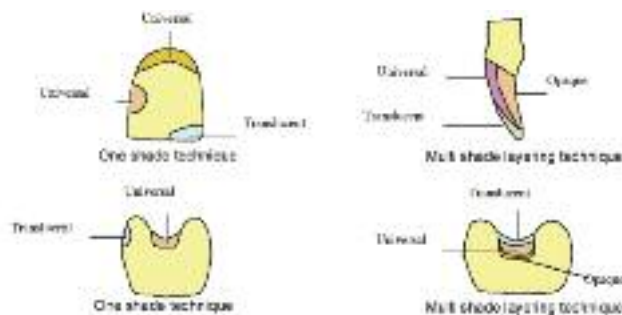
b. In the case of large and/or deep cavities

In most cases a multi shade layering technique will give the best aesthetic results. To block out shine through from the oral cavity or to mask discolored dentine, select an appropriate Opaque shade and continue to build up with a Universal shade. For optimal aesthetics use a Translucent shade as the final composite layer.

In the case of deep posterior cavities, a flowable composite such as GRADIA® DIRECT Flo / LoFlo or a glass ionomer cement such as GC Fuji LINING™ LC (Paste Pak) or GC Fuji IX™ GP can be used on the cavity floor instead of an Opaque shade.

See also Examples of Clinical Applications and/or Shade Combination Chart.

EXAMPLES OF CLINICAL APPLICATIONS (CLINICAL HINTS):



KALORE SHADE COMBINATION CHART FOR MULTIPLE LAYERS IN DEEP AND/OR LARGE CAVITIES

	A1	A2	A3	A3.5	A4	B1	B2	B3	C2	C3	D2	CV	CVD	BW	XBW
Opaque	OBW	AO2	AO3	AO3	AO4	OBW	AO2	AO3	AO3	AO4	AO2	AO4	AO4	OBW	OBW
Universal	A1	A2	A3	A3.5	A4	B1	B2	B3	C2	C3	D2	CV	CVD	BW	XBW
Translucent (Enamel)	WT	WT	DT	DT	DT	WT	WT	DT	DT	DT	WT	DT	DT	WT	WT

For details of shades, refer to the following section of SHADES.

5. Contouring before Light Curing

Contour using standard techniques.

6. Light Curing

Light cure KALORE using a light curing unit (Fig. 3). Keep light guide as close as possible to the surface.

Refer to the following chart for Irradiation Time and Effective Depth of Cure.

KALORE: Irradiation Time and Effective Depth of Cure.			
Irradiation time:	Plasma arc (2000mW/cm ²)	3 sec.	6 sec.
	G-Light™ (1200mW/cm ²)	10 sec.	20 sec.
Shade:	Halogen / LED (700mW/cm ²)	20 sec.	40 sec.
	CT, NT, WT, GT, CVT	3.0mm	3.5mm
A1, A2, B1, B2, D2, C2, XBW, BW, DT		2.5mm	3.0mm
	A3, B3, A3.5	2.0mm	3.0mm
A4, C3, AO2, AO3, AO4, CV, CVD, OBW, OXBW		1.5mm	2.5mm

Note :

1. Material should be placed and light cured in layers. For maximum layer thickness, please consult above table.
2. Lower light intensity may cause insufficient curing or discoloration of the material.

7. Finishing and Polishing

Finish and polish using diamond burs, polishing points and discs. To obtain a high gloss, polishing pastes can be used.

SHADES

26 Shades

15 Universal Shades (color code on unitip cap / syringe label: green)
XBW (Extra Bleaching White), BW (Bleaching White), A1, A2, A3, A3.5, A4, B1, B2, B3, C2, C3, D2, CV (B5:Cervical), CVD (B7:Cervical Dark)

5 Opaque Shades (color code on unitip cap / syringe label: violet)
AO2, AO3, AO4, OBW (Opaque Bleaching White), OXBW (Opaque Extra Bleaching White)

6 Translucent Shades (color code on unitip cap / syringe label: gray)
WT (White translucent), DT (Dark translucent), CT (Clear translucent), NT (Natural translucent), GT (Gray translucent), CVT (Cervical translucent)
Note : A, B, C, D shades are based on Vita® Shade.

STORAGE

Store in a cool and dark place (4-25°C / 39.2-77.0°F) away from high temperatures or direct sunlight.
(Shelf life : 3 years from date of manufacture)

PACKAGES

I. Unitips

1. Refill
 - a. Pack of 20 tips (each in 11 shades) (0.16mL per tip)
A1, A2, A3, A3.5, A4, B1, B2, B3, C2, C3, D2
 - b. Pack of 10 tips (each in 15 shades) (0.16mL per tip)
XBW, BW, CV, CVD, AO2, AO3, AO4, OBW, OXBW, WT, DT, CT, NT, GT, CVT
Note : Weight per Unitip : 0.3g
2. Option
 - a. Shade guide
 - b. Mixing pad (No.14B)

II. Syringes

1. Refill
1 syringe (in 26 shades) (2.0mL per syringe)
Note : Weight per syringe : 4g
2. Option
 - a. Shade guide
 - b. Mixing pad (No.14B)

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter can be used to isolate the operation field from the skin or oral tissue.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Take care to avoid ingestion of the material.
4. Wear plastic or rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
5. For infection control reasons, Unitips are for single use only.
6. Wear protective eye glasses during light curing.
7. When polishing the polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
8. Do not mix with other similar products.
9. Avoid getting material on clothing.
10. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge, or cotton pellet before light curing.
11. Do not use KALORE in combination with eugenol containing materials as eugenol may hinder KALORE from setting.

Last revised: 5/2009

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13.0 SUMMARY

KALORE is a state-of-the-art, direct composite resin designed for anterior and posterior direct restorations. The incorporation of the proprietary monomer DX-511 has enabled optimization of the physical properties of the composite material.

KALORE offers reduced polymerization shrinkage and polymerization stress. In laboratory testing, KALORE demonstrated the lowest shrinkage stress of all composites tested. Furthermore, this innovative direct composite resin possesses excellent handling properties, working time and curing depth. It also offers high durability, wear resistance and polishability.

KALORE gives the clinician the ability to optimize aesthetics for direct composite restorations. The availability of universal, opaque and translucent shades makes it possible to restore cavities using either a single- or multi-shade layering technique, while specialized shades are available to optimize aesthetics in cases with increased translucency, shading or bleached enamel.

Direct composite restorations with unrivaled aesthetics as well as excellent mechanical and physical properties are now possible with KALORE.

14.0 ADDENDUM

Influence of the new DuPont monomer (DX-511) on the longevity of GC KALORE

GC Corporation R&D. May 2009

Introduction

During polymerization of composite resin, the resin matrix reduces in volume while the particles retain their pre-polymerization volume. This results in stress at the filler and resin matrix interface. This stress remains within the cured composite resin and can lead to early replacement of restorations, as particles will be lost from the matrix. To reduce polymerization stress at the filler/matrix interface, lower levels of polymerization shrinkage are required.

Recently, a new low shrinkage monomer (DX-511) was licensed from DuPont by GC Corporation. DX-511 reduces volumetric shrinkage of the resin matrix and, consequently, should minimize both the generation of stress at the filler/matrix interface and the loss of particles from the resin matrix. To confirm this hypothesis, composite samples were prepared with (KALORE) and without (KALORE without DuPont) the low shrinkage monomer. Both materials were formulated with identical fillers, using the same filler sizes, distribution and treatment (Table 1).

Table 1. Formulation of KALORE and KALORE without DuPont.

Monomer Formulation	
KALORE	KALORE without DuPont
UDMA	UDMA
Dimethacrylate	Dimethacrylate
DX-511 (low shrinkage monomer)	
Fillers and Partide Sizes (identical for KALORE & KALORE without DuPont)	
Fluoroaluminosilicate glass (silanated) 700 nm	
Strontium glass (silanated) 700 nm	
Pre-polymerized filler (surface treated) 17 µm	
Silicon dioxide (silanated) 16 nm	

The following tests were conducted on both sets of samples to confirm the superior performance of KALORE and that the filler particles in KALORE are retained in the matrix:

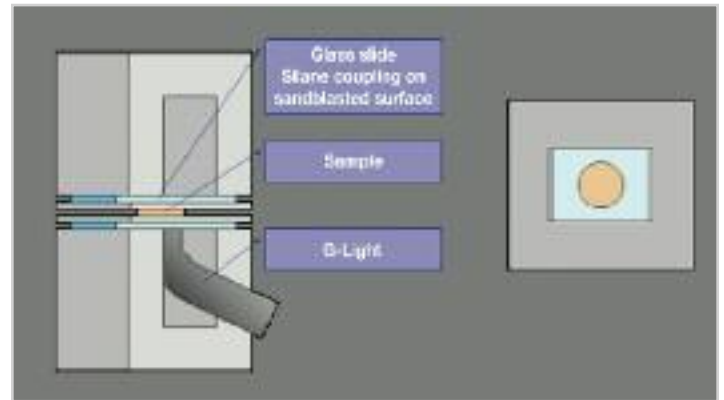
1. Shrinkage stress test
2. Three-body wear resistance test
3. Combined polish retention/surface roughness test

Materials and Methods

1. Shrinkage stress test

Setting shrinkage stress was measured in-house using a universal testing machine EZ-S (Shimadzu) with a custom-made jig. Two glass slides were pre-treated with sandblasting and a silane coupling agent, then attached to both the upper and the lower jig. A composite resin sample (1.66 mL) was placed on the lower glass slide and pressed by lowering the upper slide glass on it until a 4 mm clearance remained between the upper and lower glass slides. The sample was light-cured for 40 seconds from the underside using a G-Light 11 mm fiber rod, then light-cured for 20 seconds from above. The setting shrinkage stress was measured for 20 minutes and the highest figure reached was recorded as the shrinkage stress.

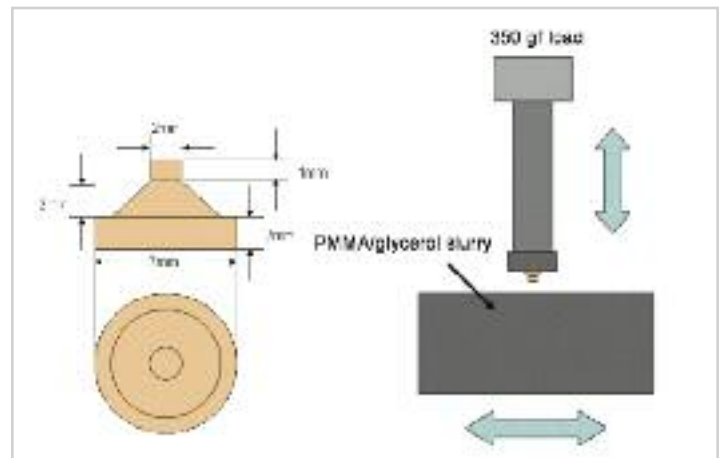
Figure 1. Universal testing machine EZ-S (Shimadzu) with custom jig.



2. Three-body wear resistance test

To measure three-body wear resistance in-house, composite specimens were prepared and moved up and down along a 5 cm path at a rate of 30 strokes per minute. They were held in indirect contact with an acrylic plate under a load of 350 gf (3.43N) and, simultaneously, the sample holder slid horizontally along a 2 cm path at a rate of 30 strokes per minute. A mixture of PMMA and glycerol (1:1 volume) was used as an intermediate abrasive. After 100,000 cycles (with one complete lateral and vertical movement being defined as one cycle), material wear was evaluated by measuring height loss. Following this test, samples of composites were processed for scanning electron microscopy (SEM) imaging.

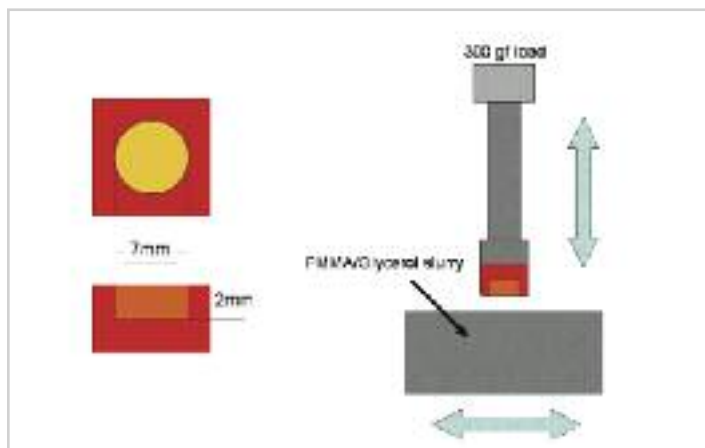
Figure 2. Three-body wear resistance test set-up.



3. Combined polish retention/surface roughness test

Composite samples were prepared in an acrylic mold and their surfaces polished using sandpaper with #80, #180, #320, #600, #1000, #1500 and #2000 grits, followed by final polishing with a buff and 1 μ m alumina. After measuring the surface gloss rates, the samples were moved up and down along a 4 cm path at a rate of 30 strokes per minute and held in indirect contact with an acrylic plate under a load of 350 gf (Fig. 3). Simultaneously, the sample holder was moved horizontally along a 2 cm path at a rate of 30 strokes per minute. A mixture of PMMA and glycerol (1:1 volume) was used as an intermediate abrasive. After 100,000 cycles (one complete lateral and vertical movement counts as one cycle, and 100,000 cycles is equivalent to between two and ten years of wear), the surface gloss was measured. Subsequently, samples of the composites were processed for SEM imaging. In addition, composite samples were scanned using confocal laser microscopy (CLSM) to assess surface roughness (Ra) before and after the polish retention test.

Figure 3. Combined polish retention/surface roughness test set-up.



Results and Discussion

Results of the shrinkage stress, wear property, polish retention and surface roughness measurements are shown in Table 2.

Table 2. Shrinkage stress, wear and surface gloss test results.

		KALORE	KALORE without DuPont
Shrinkage Stress (N)		8.3	9.5
Wear Test (μ m)		15.9 (2.3)	16.3 (5.9)
Gloss Retention (Gloss Rate) (%)	After Polish	80.1 (4.2)	76.0 (4.5)
	After Stress	78.2 (4.8)	70.4 (4.1)
Surface Roughness (Ra) (μ m)	After Polish	0.019 (0.001)	0.047 (0.008)
	After Stress	0.027 (0.004)	0.059 (0.011)

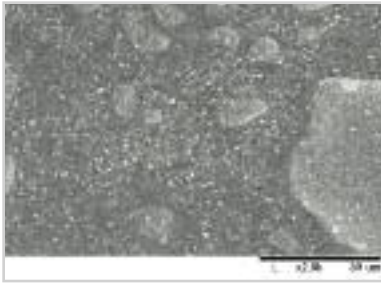
Shrinkage Stress Results

The shrinkage stress of KALORE measured 8.3N, which was 12% less than the shrinkage stress of KALORE without DuPont which was 9.5N. This test confirmed that incorporation of the new low shrinkage monomer (DX-511) reduces shrinkage stress.

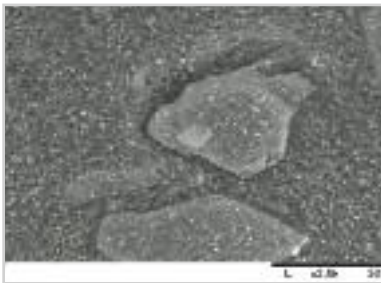
Wear Test Results

Wear data was similar for both composite materials tested, despite the fact that the glass and pre-polymerized filler particles in the KALORE without DuPont matrix were disrupted due to shrinkage forces. This can be explained by the protective action of the innovative and newly developed pre-polymerized fillers that are highly loaded with 400 nm glass filler and heat-cured. The relatively high content of pre-polymerized fillers protects the resin effectively against three-body wear (Fig. 4).

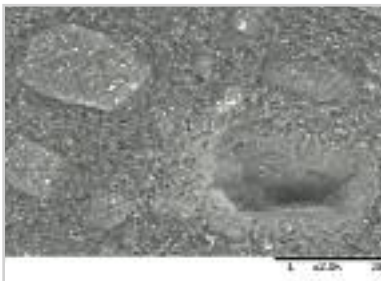
Figure 4. SEM images of KALORE with and without the DuPont matrix.



4a. KALORE x2000 after 100,000 cycles.
Note the continuous interface between the pre-polymerized fillers and the resin matrix.



4b. KALORE without DuPont x2000 after 100,000 cycles.
Note the gap at the interface between the pre-polymerized filler and the resin matrix. Additionally, voids can be observed where fillers were lost.



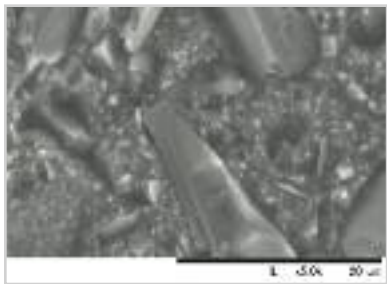
4c. KALORE without DuPont x2000 after 100,000 cycles.
Note the loss of pre-polymerized fillers and glass particles from resin matrix.

In another test, the wear resistance of KALORE was compared to a number of other composite materials. Both the wear resistance data and SEM images confirmed that materials with a higher shrinkage stress demonstrate greater particle loss from the matrix, resulting in more wear (Table 3, Fig. 5).

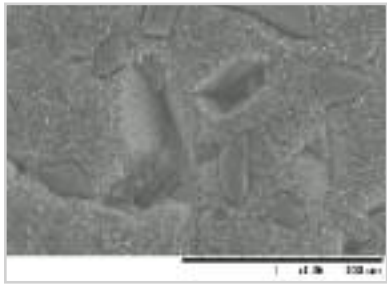
Table 3. Three-body wear and shrinkage stress.

		Three-body wear (µm) (SD)	Shrinkage Stress (N)
Estelite Quick [†] , Tokuyama	Pre-polymerized	Sample broken	10.0
Grandio [†] , Voco	Hybrid	30.2 (9.0)	11.9
Clearfil Majesty Esthetic [†] , Kuraray	Pre-polymerized	Sample broken	9.6
KALORE, GC	Pre-polymerized	15.9 (2.4)	8.3

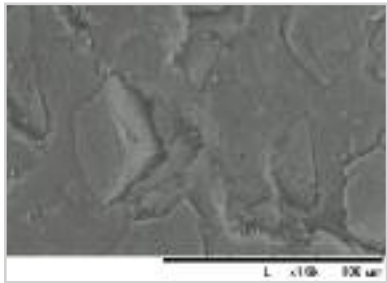
Figure 5. SEM images of other composite materials.



5a. Grandio[†] x5000 after 100,000 cycles.
Note the gaps at the interface of the glass fillers and the resin matrix. Additionally, voids can be observed where fillers were lost.



5b. Clearfil Majesty Esthetic[†] x1000 after 100,000 cycles.
Note the loss of pre-polymerized fillers and gaps at the interface of the particles and the resin matrix.



5c. Estelite Quick[†] x1000 after 100,000 cycles.
Note that the interface between the pre-polymerized fillers and the resin matrix is no longer continuous and that the fillers are no longer an intrinsic part of the matrix.

Combined Polish Retention and Surface Roughness Test Results

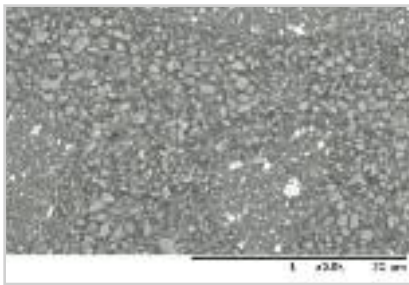
The initial surface gloss of KALORE without DuPont was lower than for KALORE, and the surface roughness was higher. Since the only difference between the two formulations was the amount of residual stress in the matrix, it was concluded that the inferior properties of KALORE without DuPont are due to greater stress on the particles with a higher risk of filler loss during the polishing procedure.

After a 100,000 cycle stress test, the KALORE formulation exhibited a slight reduction in surface gloss and a slight increase in surface roughness (Ra). It was observed from SEM images that the pre-polymerized fillers and glass fillers remained tightly adopted in the resin matrix (Fig. 6a). CLSM images demonstrated that, while slightly roughened, the surface of the KALORE material remained smooth (Fig 7).

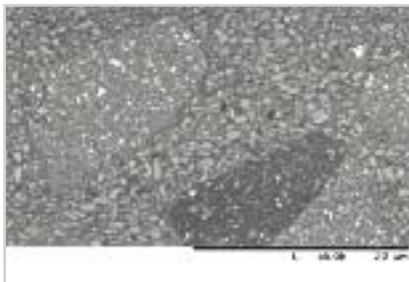
In contrast, the KALORE without DuPont exhibited an 8% reduction in surface gloss and a 25% increase in surface roughness under the same test conditions. Furthermore, SEM images demonstrated that the pre-polymerized fillers and glass fillers were disrupted from the resin matrix (Fig. 6b) and CLSM images demonstrated a rough surface (Fig. 8).

From these results, it can be concluded that the KALORE formulation can be expected to provide for long-term surface smoothness and surface gloss.

Figure 6. SEM images of KALORE with and without DuPont matrix..



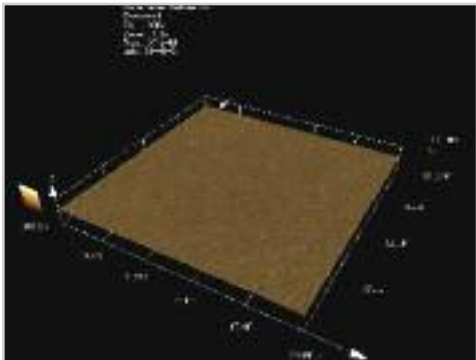
6a. KALORE x5000 after 100,000 cycles.
Note the continuous interface between pre-polymerized fillers and the resin matrix.



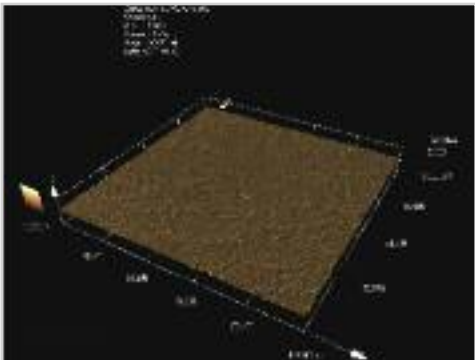
6b. KALORE without DuPont x5000 after 100,000 cycles.
Note the voids resulting from the loss of fillers from the resin matrix.

GC KALORE x2500 CLSM Images

Figure 7. CLSM images of KALORE with DuPont matrix after polish retention test.



Immediately after polishing retention test.

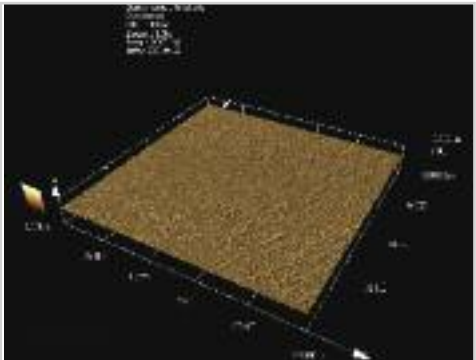


After 100,000 cycles polish.

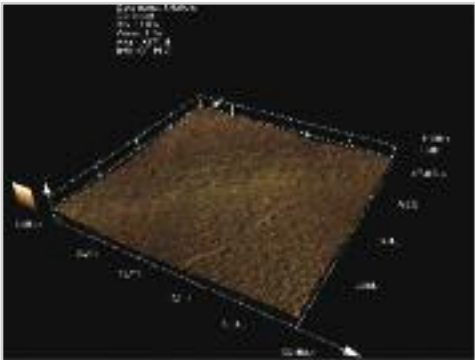
Note that although a slightly rougher surface is observed after the polish retention test, the surface remains smooth.

GC KALORE without DuPont x2500 CLSM Images

Figure 8. CLSM images of KALORE without DuPont matrix after polish retention test.



Immediately after polishing retention test.



After 100,000 cycles polish.

Note that the surface is rougher after the polish retention test.

Figure 9a. Polymerization shrinkage stress.

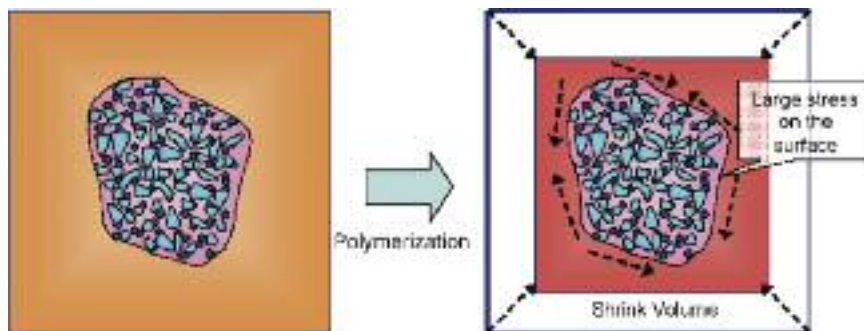
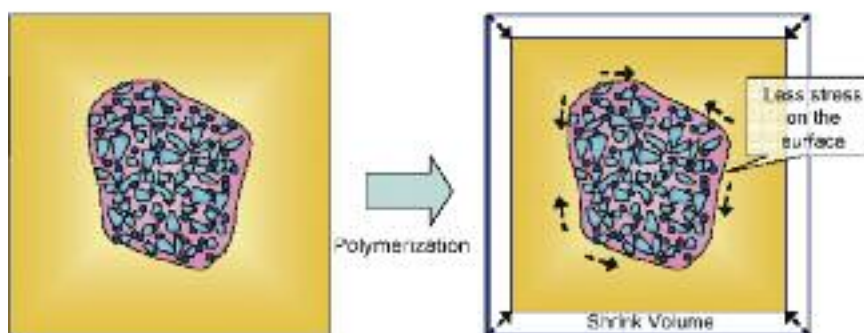


Figure 9b. Polymerization shrinkage stress with KALORE.



It can be concluded that DX-511, the new low shrinkage monomer, is effective in reducing shrinkage stress as demonstrated by testing of KALORE (Fig. 9). The reduction in ongoing stress within the composite resin helps retain fillers in the matrix, especially after stress is applied to the cured composite resin. The surface smoothness, wear resistance and polish retention were also found to be superior with the addition of DX-511 to the composite resin formulation.

In conclusion, these features contribute to increased durability and longevity of composite resin restorations.

Visit www.gcamerica.com/kalore/ for more information.



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