

3M ESPE

Ketac™ Nano

Light Curing Glass Ionomer Restorative

technical product profile

Ketac



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Introduction

Product Description

Ketac™ Nano Light Curing Glass Ionomer Restorative and Ketac™ Nano Primer is the latest development in a long history of glass ionomer technology provided by 3M ESPE to the dental profession.

Ketac Nano restorative is a new technical development that combines the benefits of a resin modified light cure glass ionomer and bonded nanofiller technology. The benefits from these two technologies provide a glass ionomer with improved polish and esthetics. Ketac Nano restorative is a two part paste, light cured resin modified glass ionomer direct restorative. The hand mix two part paste formulation is delivered from a multi-dose Clicker™ Dispenser providing faster, easier mixing than powder/liquid hand mix products.

Glass Ionomer Restorative History

For decades the dental professional has searched for an esthetic material to replace the traditional amalgam restorative, where the new restorative would exhibit wear resistance comparable to amalgams. In the search to replace amalgams, two types of restoratives emerged, composites and glass ionomers, where each in their differing ways fulfill most of the requirements of a successful restorative material. Most recently, a hybrid of composite and glass-ionomer, called compomers, has emerged, due to attempts to take advantage of the positive attributes of both composite and glass ionomers.¹

Composites have provided for an esthetic restorative; however a number of problems are associated with using dental composites, with the primary ones being polymerization shrinkage, intolerance to moisture, and lack of essential bonding to dentine and enamel. While great strides have been made in development of bonding agents, even the use of bonding systems to bond resin based materials to dentine have not been wholly successful and their adhesive forces do not always adequately counteract the polymerization contraction of the composite resin. Glass ionomer materials have been developed to solve problems existing in application of composite resin restoratives. As a result, glass-ionomers have found wide acceptance in the dental community.²

Glass ionomers are required to meet physical, chemical, biological and esthetic requirements, akin to all materials used in the mouth. Requirements for use include adequate strength, abrasion resistance, resilience, and dimensional stability during processing and subsequent use. To match the appearance of the oral hard tissue being replaced, translucency or transparency is also required. In addition good color stability, and resistance to oral fluids with which they are in contact, must exist.³

The term 'glass-ionomer' is exclusively reserved for a material consisting of an acid-decomposable glass, and water-soluble acid which sets by an acid-base reaction in the presence of water. Glass ionomer cement technology was invented by Wilson and coworkers in the UK in the 1970's. Since then glass ionomer technology has evolved into several other glass ionomer type products used in both the medical and dental fields. In the medical field for ears, nose, and throat surgery, and procedures involving craniofacial reconstruction, and in the dental field for a variety of restorative dental procedures involving cements, liner/bases under amalgam and composite restorative materials, or as a restorative alone. No matter how it's used, to be considered a glass ionomer there are certain necessary components:

- Acid functional polymer: a polycarboxylic acid
- Water
- Fluoroaluminosilicate (FAS) glass

The above components when combined react to form a true acid-base material, where the base is a fluoroaluminosilicate glass that interacts with the ionic polymeric acid and the reaction leads to a diffusion based adhesion between the glass particles and the matrix. This type of acid-base setting reaction, or curing mechanism in its simplest form has been classified as a “conventional” type glass ionomer material and one of the signature benefits of these materials is the prolonged release of fluoride.

In order to overcome some of the disadvantages of a conventional glass ionomer, but still preserve their benefits, 3M ESPE introduced the concept of a resin modified light cured glass ionomer (RMGI) to the dental community. Vitrebond™ Liner/Base was the first light cure glass ionomer liner/ base, and Vitremer™ Resin Modified Glass Ionomer Core Buildup/Restorative was introduced soon afterward. The benefits of light curing glass ionomers are well recognized, the most obvious being the cure-on-demand feature. 3M ESPE has now taken it a step further by developing a resin modified glass ionomer incorporating the benefits of nanotechnology.

Special Features

The special features of Ketac™ Nano Light Curing Glass Ionomer Restorative is the unique two part paste technology combined with nanofiller technology.

Historically, a powder and liquid needs to be mixed which initiates the acid-base setting reaction of a glass ionomer. Ketac Nano restorative was developed as a two part paste to provide faster, easier, less messy, and more reproducible dispensing and mixing compared to powder liquid systems.

Nanotechnology was used in the development to provide some value added features not typically associated with glass ionomer restorative materials. Generally glass ionomer restoratives can contain a broad range of particle sizes. Filler particle size can influence strength, optical properties, and abrasion resistance. By using bonded nanofillers and nanocluster fillers, along with FAS glass Ketac Nano restorative has improved esthetics, yet still provides the benefits of glass ionomer chemistry, such as fluoride release.

Composition

The chemistry of Ketac Nano restorative, a resin modified glass ionomer (RMGI), is based on the methacrylate modified polyalkenoic acid first commercialized in Vitrebond RMGI Liner/Base, and subsequently employed in Vitremer Core Buildup Restorative, and other 3M ESPE dental materials. This polyacid, which will be abbreviated as VBCP (Vitrebond™ Copolymer), is capable of both crosslinking via pendant methacrylate groups as well as the acid-base reaction between the FAS glass and the acrylic and itaconic acid copolymer groups. Water, essential to ionomer reactions is also present.

	VITREMER™	KETAC™ NANO RESTORATIVE
Aqueous component	De-ionized water	De-ionized water
Methacrylate component	HEMA	Blend including HEMA
Polyalkenoic acid component	VBCP*	VBCP
Filler components	FAS**	FAS, Nanomers, and Nanoclusters***
Definitions: * Vitrebond Copolymer, a methacrylate modified polyalkenoic acid ** Methacrylate functional – (FAS) Fluoroaluminosilicate glass *** All Methacrylate functional FAS, Nanomers, and Nanoclusters are surface modified		

Table 1: Qualitative compositional comparison of Vitremer™ Core Buildup/Restorative and Ketac™ Nano Light Curing Glass Ionomer Restorative

Chemistry

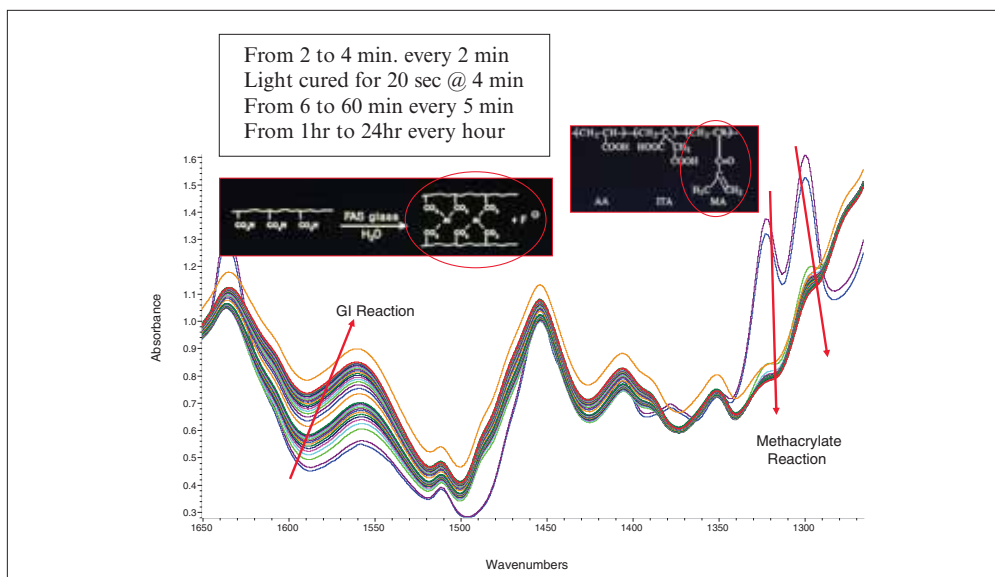
The reactions generally take place concurrently; however, free radical polymerization generally occurs at a rate significantly faster than the GI reaction. The GI setting mechanism is an ionic reaction that occurs between a basic, acid reactive fluoroaluminosilicate glass (FAS) and a polycarboxylic acid functional polymer in the presence of water. The reaction of the carboxylic acid functional groups with the basic glass results in a chemical reaction that neutralizes the acidic parts and subsequently generates distinct metal carboxylate salts. In general, this provides the basis for the glass ionomer cementation reaction and sustained fluoride release associated with this class of materials. The GI reaction in Ketac Nano restorative can be readily demonstrated after combining and mixing the two pastes. The GI reaction can be clearly monitored as a function of time by utilizing an infrared (IR) spectroscopic technique as illustrated in Figure 2. The increasing formation of an IR absorbance at 1560 cm^{-1} from $t=2$ minutes to 24 hrs demonstrates an initial and an ongoing GI reaction typical of materials in this category.

A second signature reaction associated with RMGI materials is the free radical polymerization of methacrylate functional monomers, oligomers and polymers. These molecules consist of reactive double bonds that exhibit characteristic infrared absorbance's at approximately 1300 cm^{-1} and 1320 cm^{-1} respectively. Upon free radical generation via a light cure mechanism, these double bonds are consumed during the polymerization process. Subsequently, the absorbance associated with these double bonds decreases linearly as a function of their decreasing concentration.

Figure 2 illustrates a sample of Ketac Nano restorative that was irradiated for 20 seconds with a dental curing light and then monitored for double bond conversion as a function of time from $t = 2$ minutes to 24 hrs. The consumption of double bonds is extremely rapid under this set of conditions with a majority being converted within 4 minutes of light exposure. Additional free radical polymerization occurs during the next 24 hours, however it is relatively minimal when contrasted to the significantly slower GI reaction process. Thus the IR analysis clearly demonstrates that Ketac™ Nano Light Cure Glass Ionomer Restorative is a true RMGI material that undergoes both GI and free radical reactions similar to other RMGI compositions.

Figure 2: Ketac™ Nano Light
Curing Glass Ionomer
Restorative FTIR versus
Time

Source: 3M Data



Fillers

The filler content of the system consists of an acid reactive fluoroaluminosilicate glass (FAS) and a unique combination of nanofillers. The filler loading is approximately 69% by weight of which the relative proportions of the two filler types are approximately 2/5 and 3/5 respectively. All of the nano fillers are further surface modified with methacrylate silane coupling agents to provide covalent bond formation into the free radically polymerized matrix. The FAS glass is radiopaque, has an approximate particle size of less than 3 microns (average particle size approximately 1 micron), and provides the basis for the glass ionomer reaction and extended fluoride release in the presence of water and a polycarboxylic acid functional polymer.

In addition, the Ketac Nano “nano-ionomer” restorative further contains a unique combination of two types of surface treated nanofillers (approximately 5-25 nm) and nanoclusters (approximately 1.0 to 1.6 microns). Nanofillers are discrete nonagglomerated and non-aggregated fillers of 5-25 nms in size. The methacrylate functionalized nanofillers in this composition include those chemically derived from both silica and zirconia. The nanocluster fillers are loosely bound agglomerates of nano-sized zirconia/silica that appear as a single unit enabling higher filler loading, radioopacity, and strength.

3M Corporate Research Analytical Laboratory produced SEMs of the fillers used in three resin modified glass ionomers. The x25,000 magnifications give the best differentiation between the 3 products relative to the presence of nanofillers. Vitremer™ Core Buildup/Restorative, and Fuji™ II LC have large filler particles, whereas the SEM of Ketac Nano restorative depicts the combination of nanofillers, nanoclusters, and FAS glass.

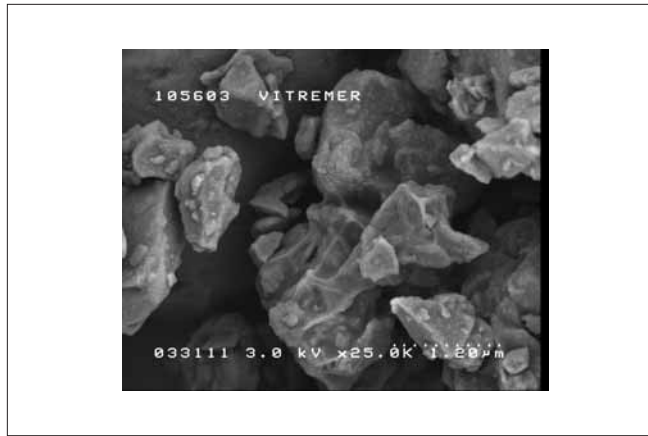


Figure 3: Vitremer™ Core Buildup/Restorative

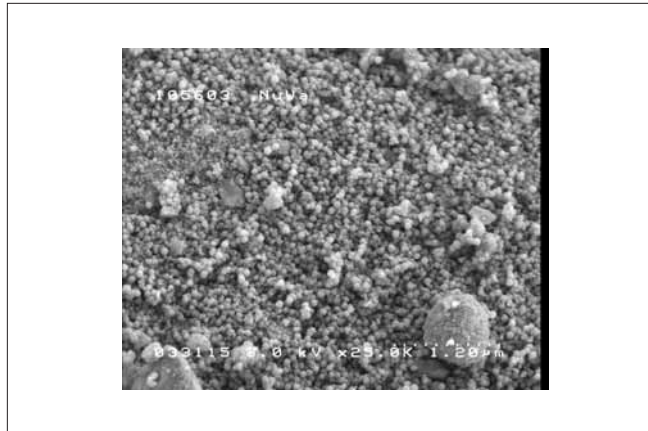


Figure 4: Ketac™ Nano Light Curing Glass Ionomer Restorative

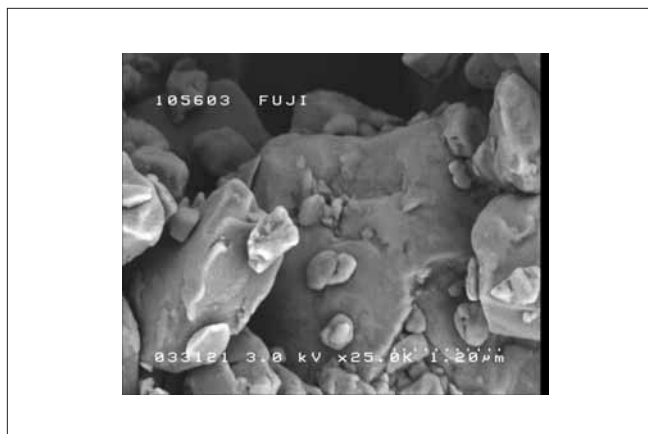
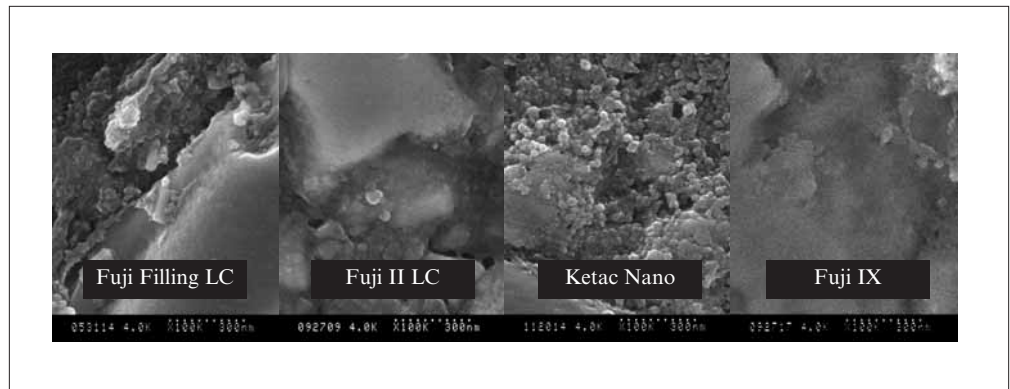


Figure 5: Fuji II™ LC Resin Modified Glass Ionomer Restorative

Some in-vitro studies have also demonstrated the addition of nanofillers provides enhanced surface wear and polish relative to some other commercially available dental materials.^{4,5} Ketac™ Nano Light Curing Glass Ionomer Restorative's unique combination of bonded nanofillers, nanoclusters, and FAS glass particles provides benefits like esthetics and enhanced polish, along with fluoride release common to these types of materials.

The images in Figure 6 of cured glass ionomer samples polished with Sof-Lex™ Discs were provided by Dr. William Douglas and Dr. Daranee Tantibirojn at the University of Minnesota. They illustrate the differences of the filler particles in their cured matrices between Fuji Filling LC and Fuji II™ LC, resin modified glass ionomers; Ketac™ Nano Light Curing Glass Ionomer Restorative; and Fuji IX™ a conventional glass ionomer. Images were generated using scanning electron microscopy, and are shown at a magnification of x100k.

Figure 6: SEM's of Polished Surfaces x100k



In summary Ketac Nano restorative is composed of a combination of unique fillers that provide benefits associated with conventional glass ionomers, resin modified glass ionomers, and nanofilled composites.

Ketac™ Nano Light Curing Glass Ionomer Restorative is comprised of a:

Two part system

Aqueous paste (acidic polyalkenoic acid, reactive resins and nano fillers)

Non aqueous paste (FAS glass, reactive resins, and nano fillers)

Filler content (69%)

27% FAS glass (acid and free radically reactive)

42% methacrylate functionalized nano fillers (acid and free radically reactive)

Cure and Setting reactions

Light curing (required)

Long term glass ionomer reaction (water, glass ionomer filler, polyacid, monomers, initiators)

Ketac™ Nano Primer

Ketac Nano primer is a one part, visible light-cure liquid specifically designed for use with Ketac Nano restorative. It is comprised of the Vitrebond™ copolymer, HEMA, water, and photoinitiators. The primer is acidic in nature. Its function is to modify the smear layer and adequately wet the tooth surface to facilitate adhesion of Ketac Nano restorative to the hard tissue. In use, Ketac Nano primer is applied to the surface for 15 seconds, and air dried. The primer is then light cured for 10 seconds. Adequately air drying followed by light curing of the primer before placement of Ketac Nano restorative provides adhesion to tooth structure.

Properties

Following is a presentation of the key properties of Ketac™ Nano Light Curing Glass Ionomer Restorative system. 3M ESPE applied patented techniques, materials and nanotechnology, and designed a paste/paste product with esthetics and shading similar to composite restoratives while maintaining the other properties of a resin modified glass ionomer.

Ketac Nano restorative was tested and found to be in compliance with ISO standard 9917-2 for “Dental Water-based Cements, Light Activated Cements,” Type II. The standard includes tests such as sensitivity to ambient light, depth of cure, flexural strength, radiopacity, opacity, and shade and color stability. Additional physical property tests were also conducted and some are referenced in this section. Testing was conducted by 3M ESPE unless otherwise noted.

Much of the information will be presented in graphical form. Comparisons to Ketac™ Nano Light Curing Glass Ionomer restorative will be made with 3M ESPE Vitremer™ Core buildup/ Restorative, and the major competitive products. Some additional comparisons will be made to composite materials.

Conventional setting glass ionomer products

- Fuji IX™ (GC International)
- Ionofil® Molar (VOCO)

Light cure resin modified glass ionomer restorative products

- Fuji II™ LC (GC International)
- Fuji Filling™ LC (GC International)
- Vitremer™ Core Buildup/Restorative (3M ESPE)

Composites

- Filtek™ Z250 Universal Restorative (3M ESPE)
- EsthetX™ (Caulk Dentsply)
- Tetric EvoCeram® (Ivoclar Vivadent)

With the exception of the composites all products were stored wet until tested.

Compressive and Diametral Tensile Strength

Compressive and diametral tensile are two common measurements of dental restorative materials. For compressive strength tests a sample of material is placed under a load that compresses it at opposite ends. The load tends to compress, or shorten it. Failure is the result of shear and tensile forces.

Compressive Strength

Shown graphically in Figure 7 are compressive strength values for various conventional, and resin modified glass ionomer restorative materials. Ketac™ Nano restorative has a higher compressive strength compared to most other glass ionomer restorative materials.

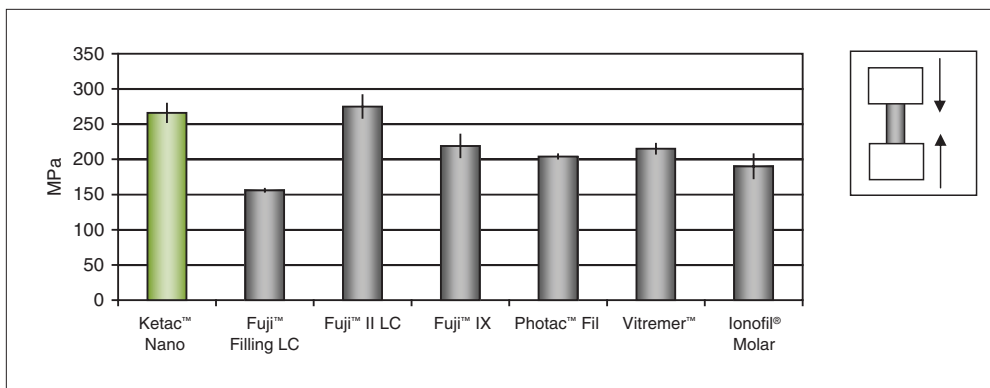
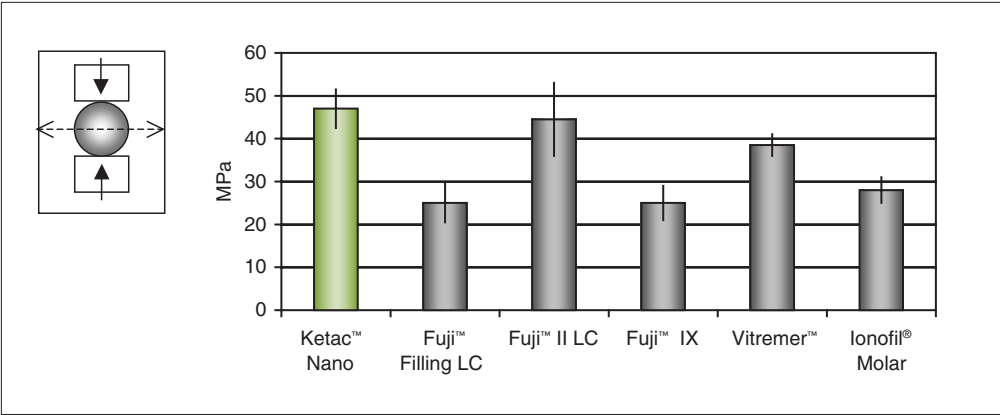


Figure 7: Compressive Strength

Diametral Tensile

Diametral tensile strength is measured using a similar test method. Forces are applied to the sides of the sample until fracture occurs. The diametral tensile strength of various materials is shown in Figure 8. Ketac Nano Restorative diametral tensile strength is statistically greater than conventional glass ionomers and comparable to other resin modified glass ionomer restoratives.

Figure 8: Diametral Tensile Strength

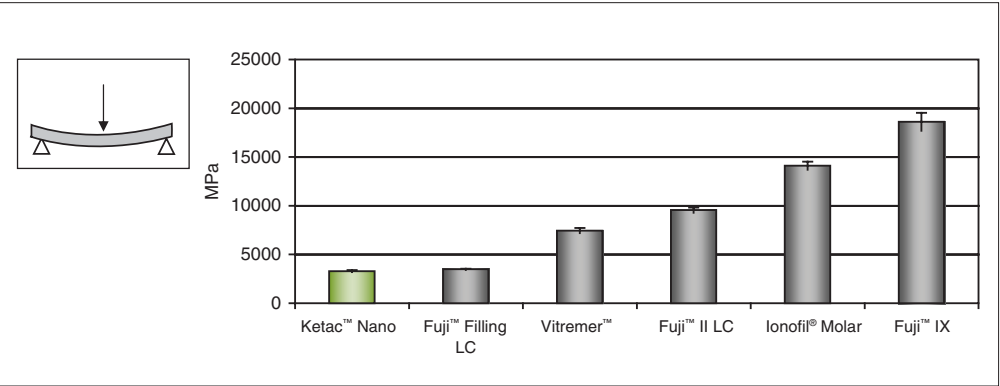


Flexural Modulus

Historically, glass ionomers have the reputation of being a brittle material. Flexural modulus is a method of defining a materials stiffness. The flexural modulus is measured by applying a load to a material specimen that is supported at each end. A low modulus indicates a flexible material.

As shown in Figure 9 conventional setting glass ionomers exhibit a higher flexural modulus than resin modified glass ionomers. Ketac Nano Light Curing Glass Ionomer Restorative exhibits a lower modulus (less brittle) than the majority of both resin modified and conventional glass ionomers.

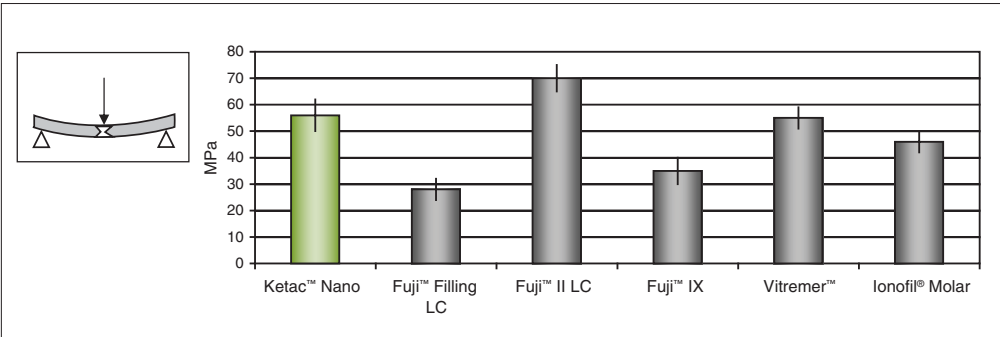
Figure 9: Flexural Modulus



Flexural Strength

Flexural strength is determined in the same test as flexural modulus. Flexural strength is the value obtained when the sample breaks. This test combines the forces found in compression and tension. In Figure 10 the data indicates that flexural strength of glass ionomers can vary. The flexural strength of Ketac Nano Restorative is comparable to Vitremer.

Figure 10: Flexural Strength



Three Body Wear

The measurement of wear is critical as an indicator of longevity in a restoration. 3M ESPE uses the three-body wear machine for internal studies. In this test a restorative material (1st body) is loaded onto a wheel which contacts another wheel (2nd body) which acts as an “antagonistic cusp”. The two wheels counter-rotate against one another dragging an abrasive slurry (3rd body) between them. Dimensional loss is determined by profilometry that measures the volumetric loss and maximum depth at regular intervals (i.e. every 20,000 cycles). The higher the value bar the less abrasion proof the material.

Figure 11 graphically depicts the wear depth of some resin modified glass ionomers. In this test Ketac™ Nano Light Curing Glass Ionomer Restorative is lower (more wear resistant) than the leading resin modified glass ionomers.

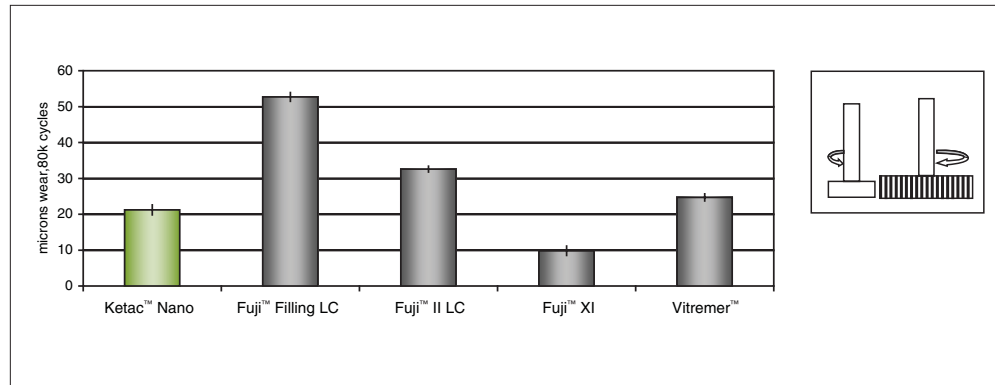
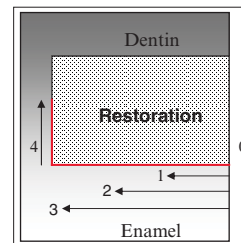


Figure 11: Total Wear Depth (80,000 cycles)

Microleakage

Microleakage studies were conducted by Dr. Tantibirojn from the University of Minnesota Dental Research Center for Biomaterials and Biomechanics (MDRCBB). Restorations were placed in extracted human teeth with margins in enamel and dentin using the manufacturer’s instructions for use. Samples were thermocycled from 5°C to 55°C for approximately 24 hours and then immersed in a dye solution for 24 hours. Teeth were removed, sectioned and measured using the following scale:

- 0 = no leakage
- 1 = less than one-third
- 2 = one third to two-thirds
- 3 = greater than two-thirds but within surrounding wall
- 4 = involve axial wall



As seen in Figure 12 microleakage comparing Ketac Nano restorative to another leading resin modified glass ionomer were comparable at the enamel and dentin interface.

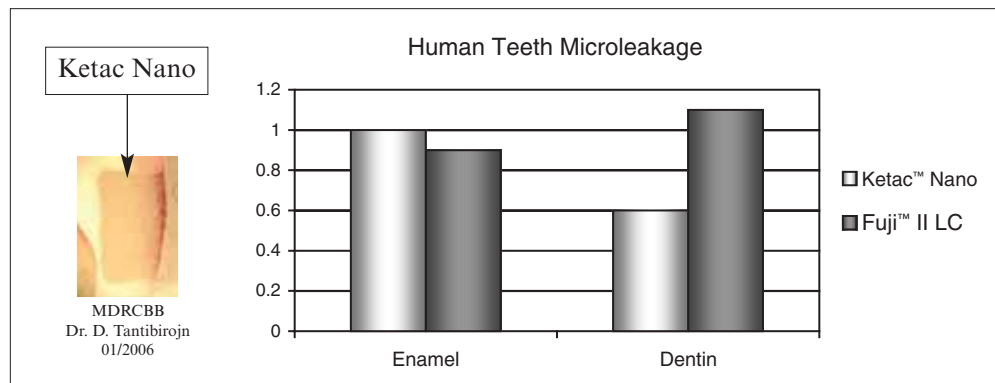


Figure 12: Human Teeth Microleakage

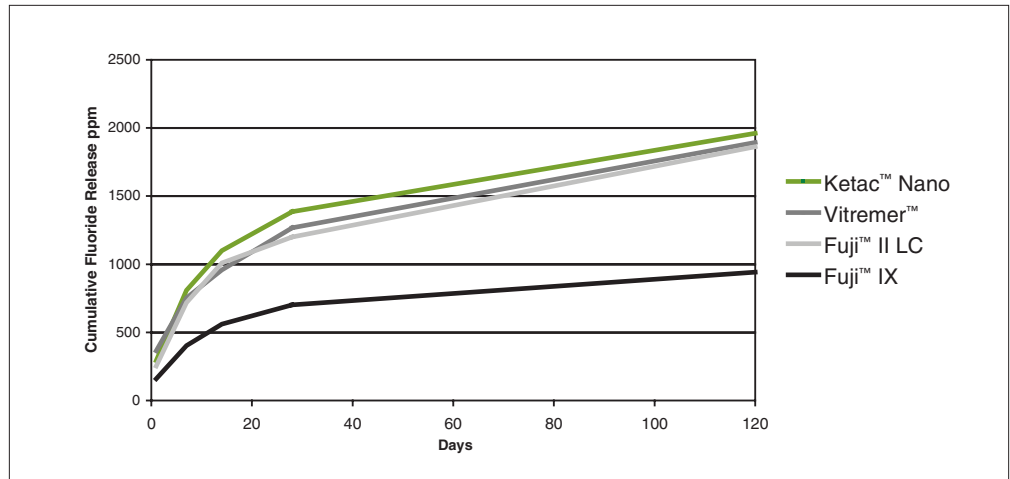
Fluoride Release

Fluoride uptake in enamel has long been known to have a caries preventive effect.⁶ The clinical cariostatic effect of glass ionomers is reported in a five year clinical study by M. Tyas.⁷ A report from the CDC published in 2001 establishes the important role of fluoride in prevention and control of dental caries.⁸

Fluoride release is measured in-vitro in buffer solutions using a fluoride ion specific electrode. In Figure 13 Ketac™ Nano Light Curing Glass Ionomer Restorative shows a high fluoride release.

Additionally, but not shown here, in-vitro tests showed Ketac Nano restorative has the ability to recharge the fluoride release after application of a topical fluoride source.

Figure 13: Cumulative Fluoride Release



Dentin and Enamel Adhesion

One of the most important characteristics of glass ionomer materials is their ability to adhere chemically to mineralized tissues negating the use of an traditional etch, prime and bond system typically used for composites. Glass ionomer restoratives characteristically require a conditioner, or a primer, such as Vitremer™ Primer to clean and adequately wet the prepped surfaces. Glass ionomers typically fail cohesively within the ionomer and thus reported adhesion is not necessarily true bond strengths. However, the glass ionomers have been shown to be highly retentive clinically. Therefore their use as effective restorative materials should not be ruled out on the basis of in-vitro bond strength data.

3M ESPE tests adhesion by placing bovine or human teeth in methyl methacrylate, then grinding and polishing these to expose enamel and dentin. The enamel or dentin surfaces are then treated in accordance with the manufacturers' instructions for bonding. A Teflon mold 5mm in diameter, and 2mm in height is placed over the treated surface. The test material is mixed, placed in the mold to form a button and cured. The light cure materials are cured by light exposure and the self cure materials allowed to sit for their recommended set time at 37°C and 80 % relative humidity. They are then placed into water at 37°C before shear bond strength is determined at a cross head speed of 1mm/min. in an Instron Universal testing machine.

Ketac™ Nano Primer is required for use with the Ketac™ Nano Light Curing Glass Ionomer Restorative to assure adequate adhesion to tooth structure. The effect of Ketac™ Nano Primer on the adhesion of Ketac Nano restorative to enamel and dentin is presented in Figure 14 and 15. Ketac Nano restorative exhibits adhesion values equivalent to most glass ionomer restoratives.

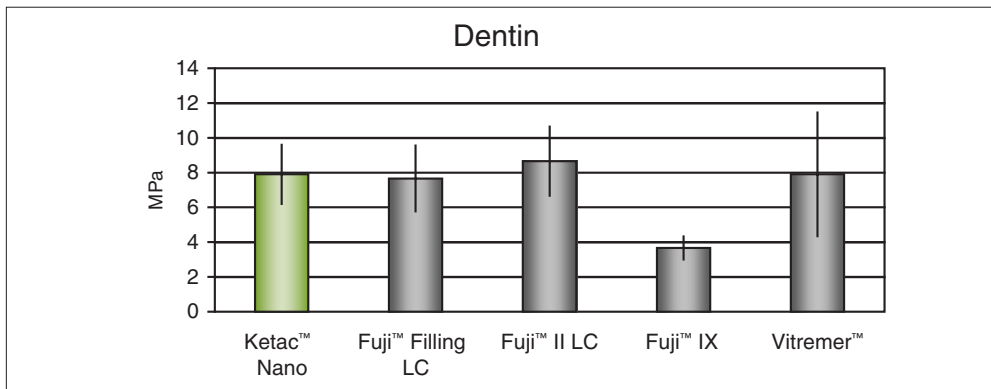


Figure 14: Adhesion to Bovine Dentin

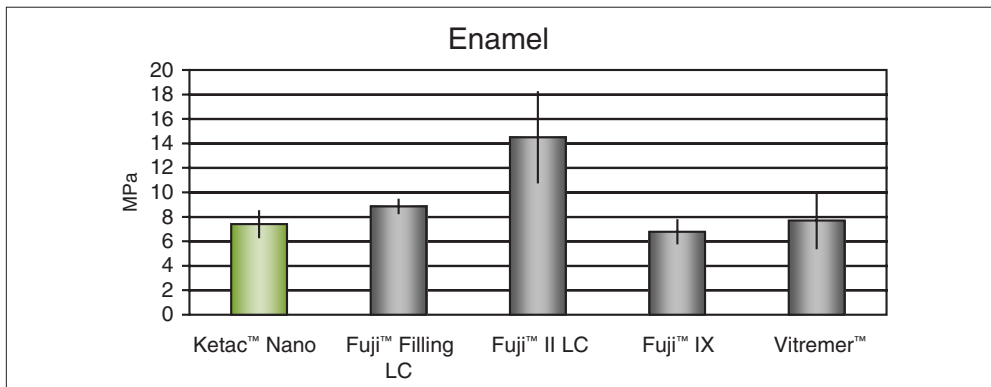
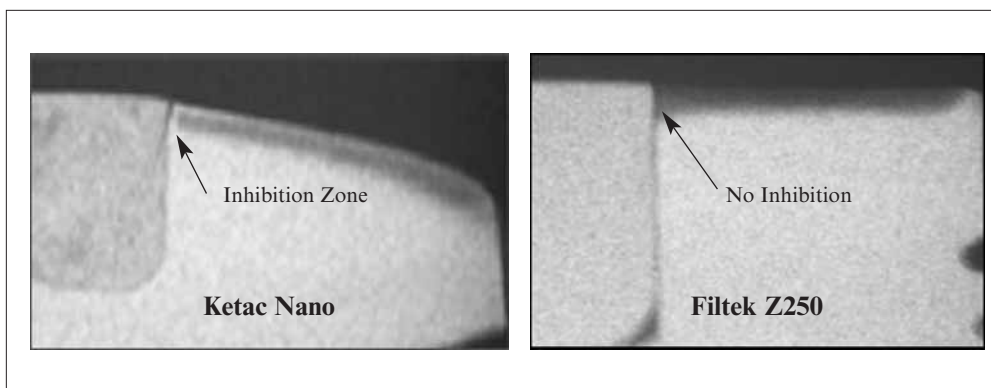
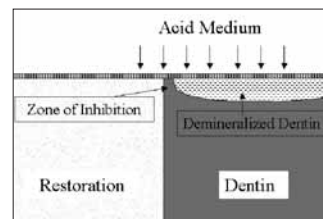


Figure 15: Adhesion to Bovine Enamel

In-Vitro Caries Inhibition

An in-vitro artificial caries inhibition test^{9,10} was conducted by the University of Minnesota MDRCB to observe any inhibition demonstrated with Ketac[™] Nano Light Curing Glass Ionomer Restorative and a composite material. Restorations of both materials were placed in bovine roots and exposed to a lactic acid gel for 3 weeks. Samples were sectioned and exposed to microradiography. The width of the inhibition zone was then measured and computed. Figures 16 and 17 illustrate after three weeks in lactic acid gel Ketac Nano restorative demonstrates an artificial caries inhibition effect, and that it is significantly different than the composite, Filtek[™] Z250 Universal Restorative, a non-fluoride releasing restorative material.



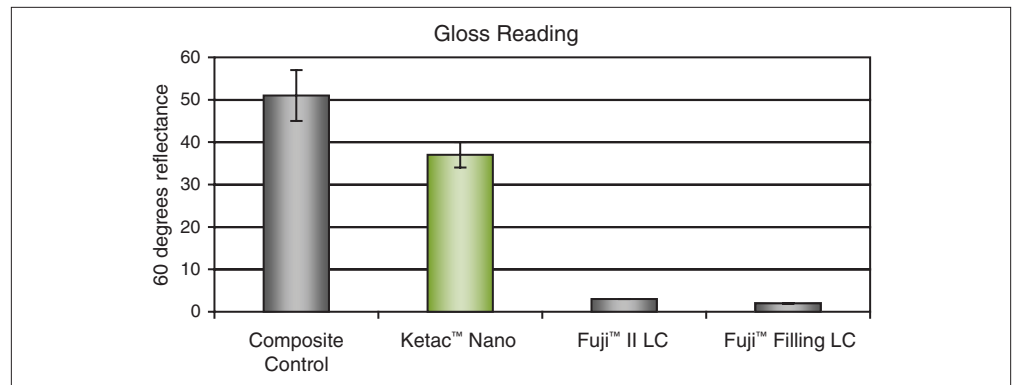
Figures 16-17: MDRCB In-vitro Demineralization Study. 11/2006

Polish

Cured samples of glass ionomer materials and a composite were prepared by laboratory light press between polyester films. Cured samples were then stored in a humidity chamber for one hour just prior to being tested. Samples were removed and polished by a single operator with a medium Sof-Lex™ Disc to imitate the surface of a restoration after being contoured. Following the Sof-Lex disc each sample was polished wet with a two- step rubber, diamond impregnated polishing system. A Rhopoint™ Novo-Curve Gloss Meter was used to collect multiple gloss reflectance readings at 60° geometry following polishing. Additionally a surface analysis using Atomic Force Microscopy (AFM) was conducted on the polished surface to record roughness parameters.

Figure 18 shows the gloss recordings taken after polishing with a diamond impregnated polishing system. The gloss recordings show an initially high polish. Close to a composite and superior to some other resin modified glass ionomers.

Figure 18: Gloss Reflectance



AFM Surface Analysis Results Following Toothbrush Abrasion and Polishing

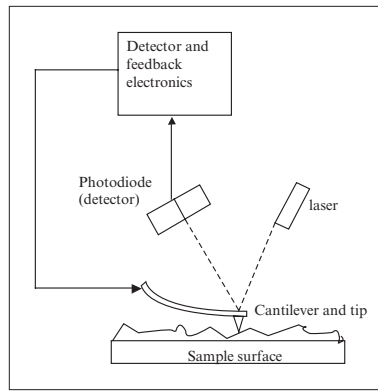
Toothbrush Abrasion Method

Cured samples of various glass ionomer restoratives are polished with a Buehler ECOMET 4 variable speed grinder-polisher and with an AUTOMET 2 polishing head. The following sequence of abrasives were used for each sample, 320 grit and 600 grit silicone carbide abrasive, 9mm diamond polishing paste, 3mm diamond polishing paste, and finally a Master Polishing Solution. This prodigal provides an ideal gloss surface prior to toothbrush abrasion.

The highly polished samples of Ketac™ Nano Light Curing Glass Ionomer Restorative, Fuji II LC, Fuji Filling LC and a composite, Tetric EvoCeram, were brushed with a soft toothbrush and Crest® Cavity Protection Regular (Proctor&Gamble) toothpaste for a total of 2000 strokes. The toothbrush and sample were mounted on a device that controlled the stroke length and force on the toothbrush head. After toothbrush abrasion 3M ESPE Central Research Analytical Laboratory subjected each sample to topographical study using Atomic Force Microscopy.

Atomic Force Microscopy

Atomic force microscopy (AFM) is a method of measuring surface topography on a scale from angstroms to 100 microns. The technique involves imaging a sample through the use of a probe, or tip, with a radius of 20 nm. The tip is held several nanometers above the surface using a feedback mechanism that measures surface-tip interactions on the scale of nano Newtons. Variations in tip height are recorded while the tip is scanned repeatedly across the sample, producing a topographic image of the surface.



Surface Roughness

Ra is the universally recognized, and most used, international parameter of surface roughness. It is the arithmetic average deviation of peaks and valleys of a surface from the mean line. Rq determines the root-mean-square value of roughness corresponding to Ra. Rq has the greatest value in optical applications where it is directly related to the optical quality of a surface.

In figures 19 and 20 two atomic force microscopy roughness parameters are illustrated.

As shown in Figure 19, Ketac™ Nano Light Curing Glass Ionomer Restorative roughness values after toothbrush abrasion is similar to a composite, and superior to some resin modified glass ionomers.

Figure 20 illustrates the surface roughness after polishing with a diamond impregnated finishing and polishing system. The surface is slightly below a composite and again better than some other resin modified glass ionomers.

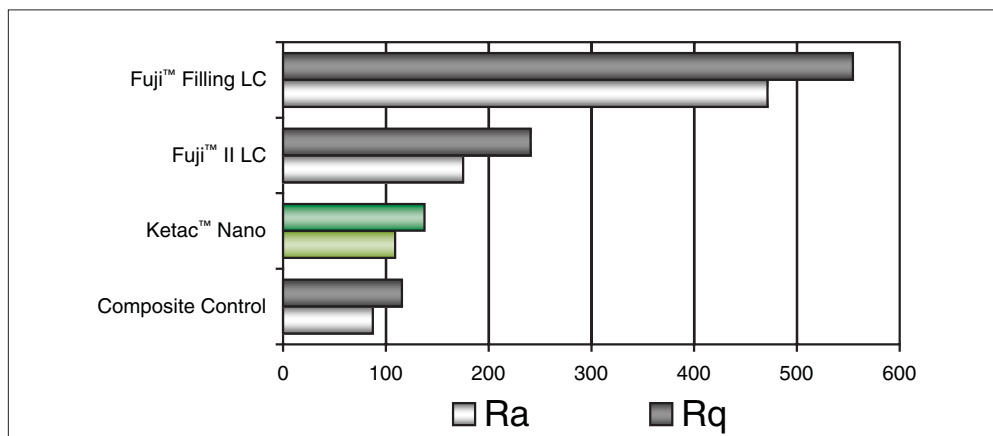


Figure 19: Roughness Parameters after Toothbrush Abrasion

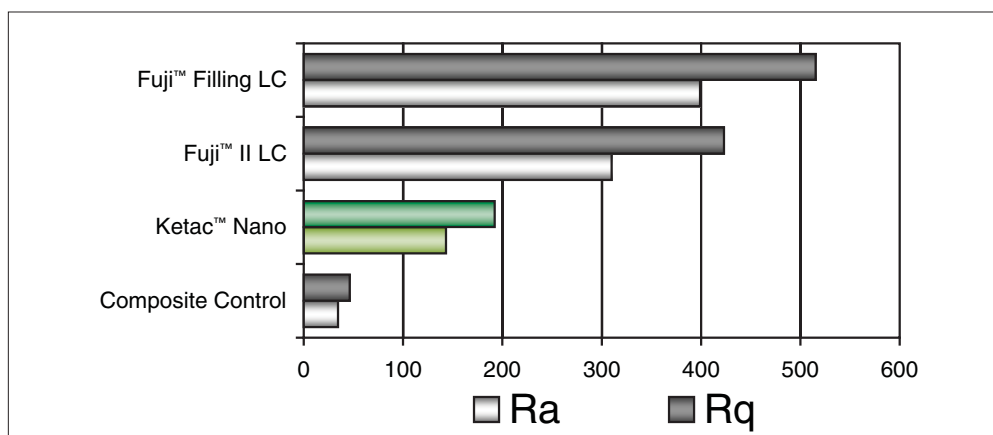


Figure 20: Roughness Parameters after Polishing

Atomic Force Microscopy Imaging

The AFM's clearly demonstrate the GC Fuji™ glass ionomer restoratives surfaces are markedly different than Ketac™ Nano Light Curing Glass Ionomer Restorative. For the GC products large filler particles are protruding and craters are evident as the result of the toothbrush abrasion and polishing. With the Ketac Nano restorative, and composite material the surfaces have remained relatively smooth.

The color bar topographically distinguishes between the high peaks and lower valleys.



Figures 21 - 24 show AFM image recordings of surfaces after 2000 abrasive toothbrush strokes.

Figure 21: Fuji™ Filling LC

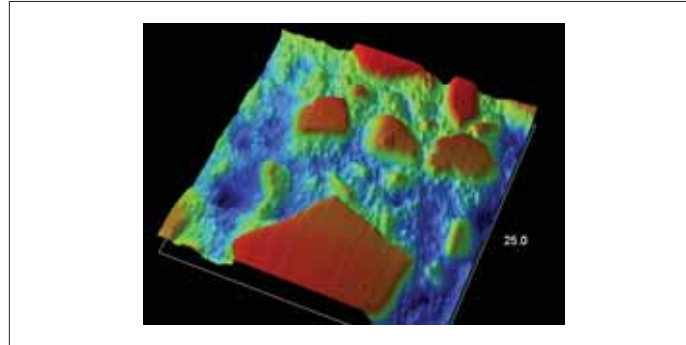


Figure 22: Fuji™ II LC

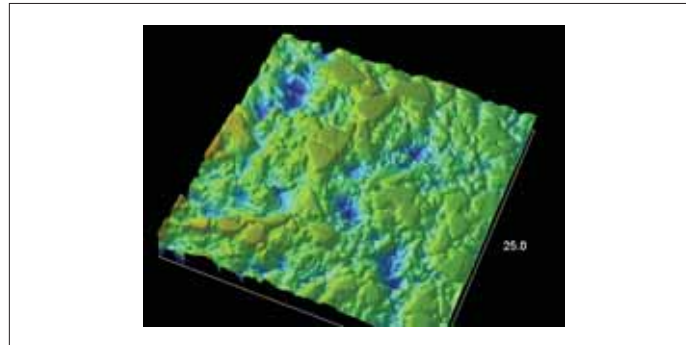


Figure 23: Ketac™ Nano

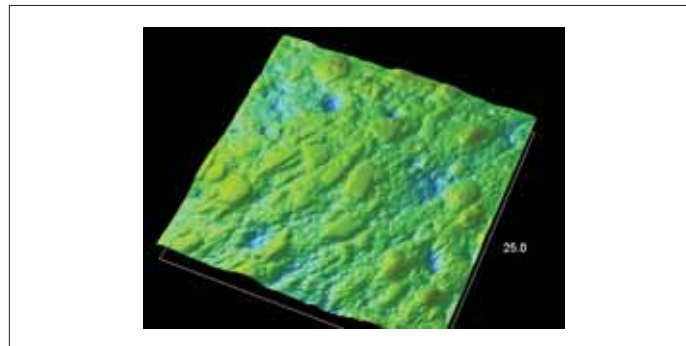
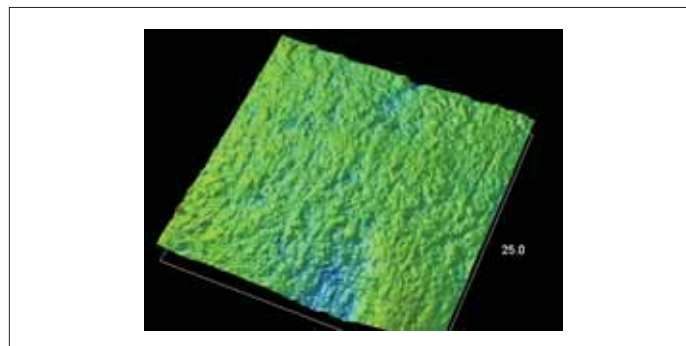


Figure 24: Composite Control



Figures 25 - 28 show AFM image recordings of surfaces after polishing with two-step polishing system.

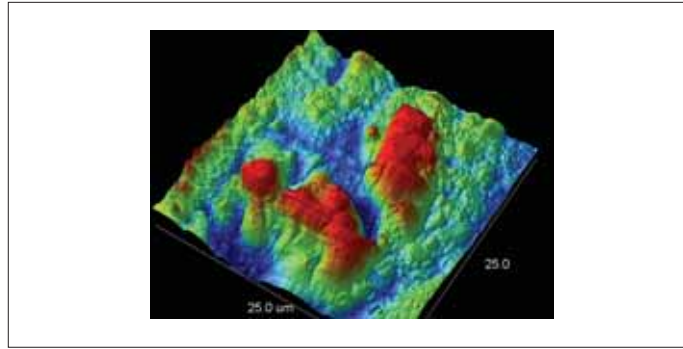


Figure 25: Fuji™ Filling LC

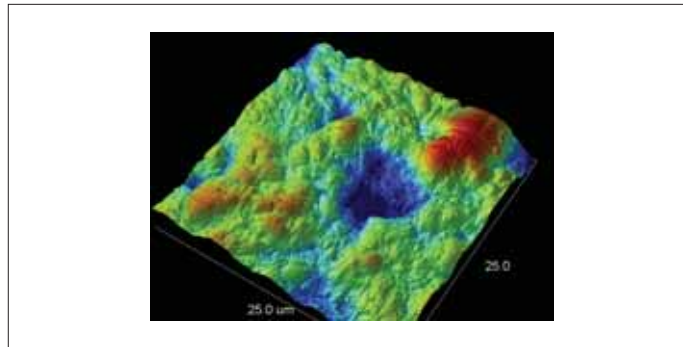


Figure 26: Fuji™ II LC

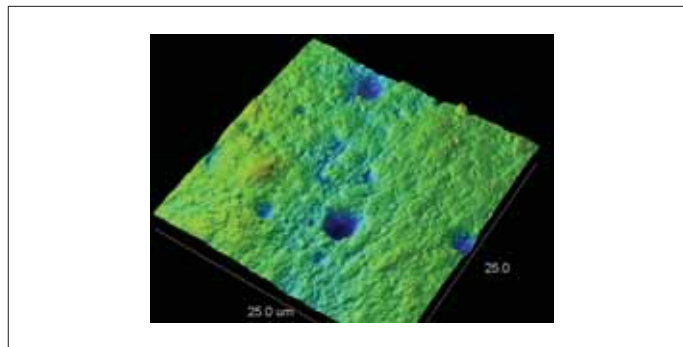


Figure 27: Ketac™ Nano

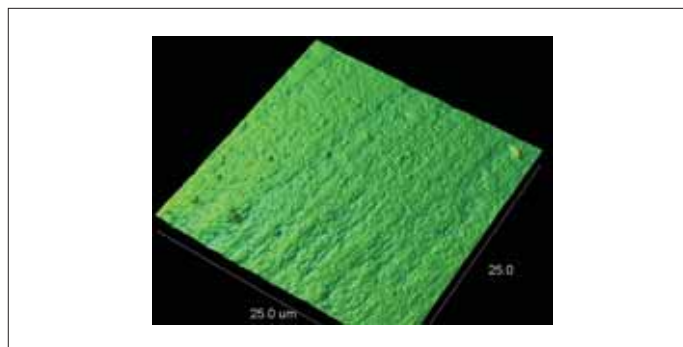


Figure 28: Composite Control

Field Evaluation

In a field evaluation, 103 dentists in the United States evaluated Ketac™ Nano Light Curing Glass Ionomer Restorative. After utilizing Ketac Nano restorative in their practices for several weeks they completed a questionnaire to report their experiences with the use of this product and how it compared to their current glass ionomer material.

Evaluators were asked to rate the preparation and the delivery of Ketac Nano restorative compared to their current powder/liquid glass ionomer restorative on a scale of “1 strongly disagree” to “5 strongly agree”. The average ratings for preparation are given in Figure 29 with results showing an improvement over hand mix powder liquid systems. In Figure 30 they compared the Clicker™ delivery of the paste to powder liquid systems. On average the evaluators agreed when compared to their current product this was better.

Figure 29: Average Comparative Ratings For Preparation

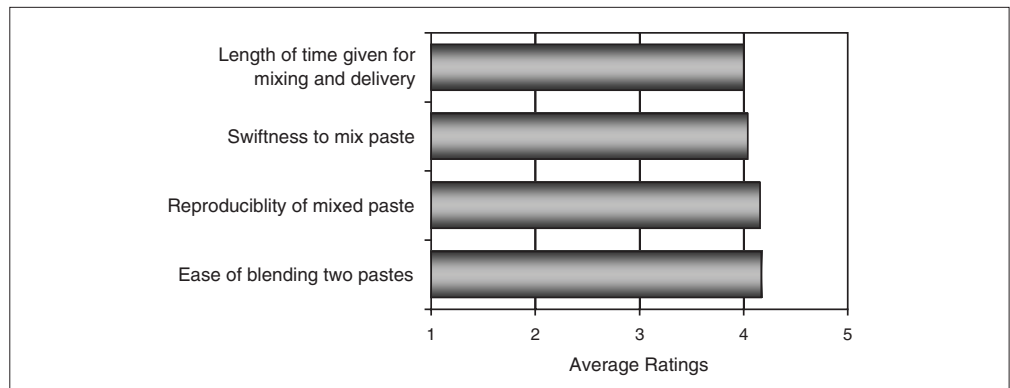
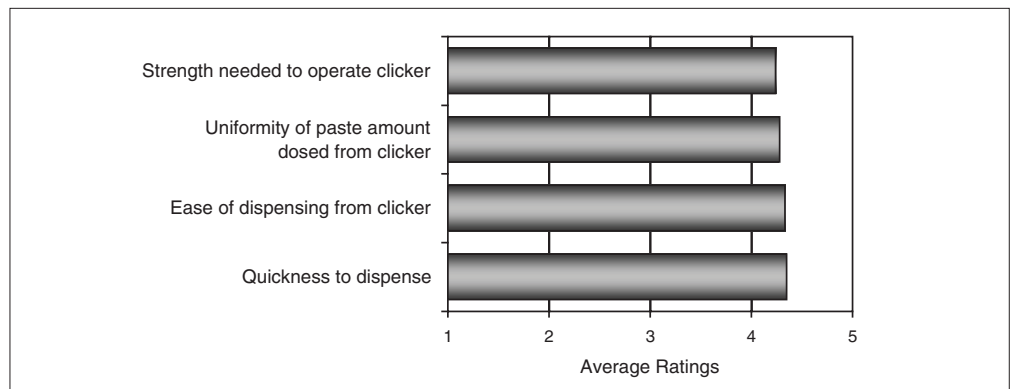


Figure 30: Average Comparative Ratings for Delivery



Each dentist was asked to compare certain features of their current glass ionomer material to Ketac Nano restorative. These features, listed in Figure 31, align to the esthetics of a dental restorative. A 5 point scale was used, where a rating of 1 was significantly worse and a 5 was significantly better. Figure 31 shows the average comparative rankings given to these features. Ketac Nano restorative on average rated higher compared to their current glass ionomer material.

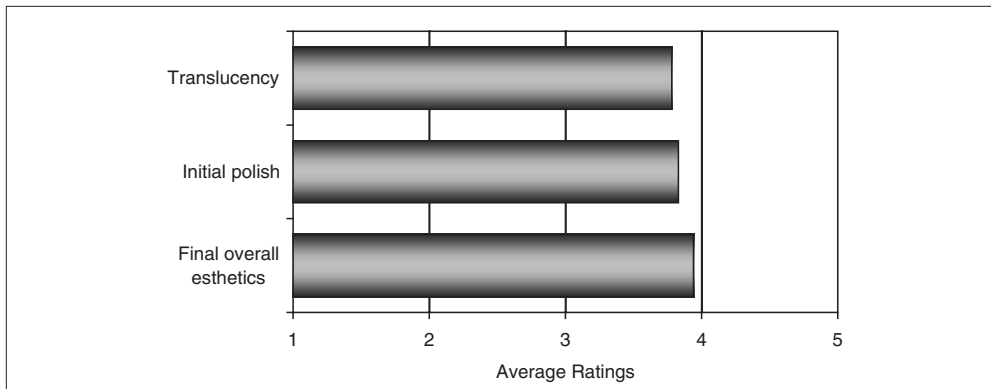


Figure 31: Average Comparative Ratings for Esthetics

Composites materials have a reputation for being the most esthetic direct restorative material a dentist can use to replace hard tooth structure. Glass ionomers have the reputation of being less esthetic. In Figure 32 dentist were asked to rate the final overall esthetics of Ketac™ Nano Light Curing Glass Ionomer Restorative compared to their current composite restorative material, 67 percent rated it the same or better.

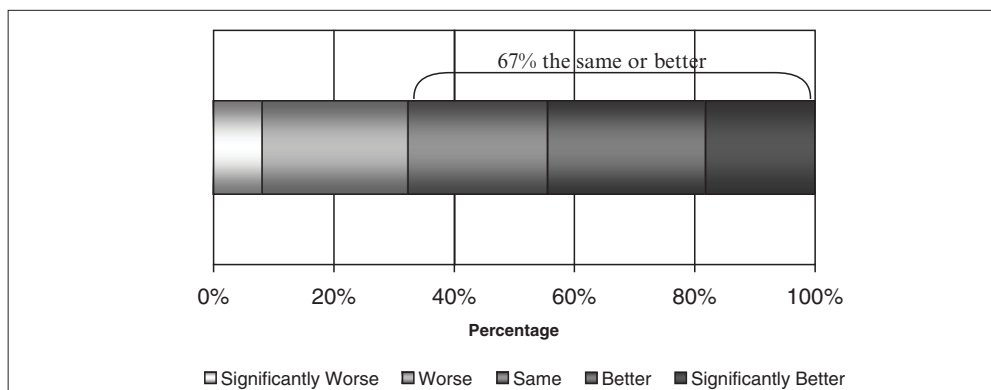


Figure 32: Esthetics of Ketac Nano vs Composites

Indications

Glass ionomers are an important part of every day dental practice. Their unique properties ensure them a continuing place in every clinician's armamentarium. Typical clinical situations where a glass ionomer restorative material is ideal.

- High caries risk patients / root caries lesions
- Pediatric patients, especially an uncooperative child
- Erosion lesions with no mechanical preparation
- Transitional restorations e.g. prior to preparation for crowns, temporary restorations, tooth trauma.

The indications for Ketac Nano Light Curing Glass Ionomer Restorative are:

- Primary teeth restorations
- Small Class I restorations
- Class III and V restorations
- Transitional restorations
- Filling defects and undercuts
- Laminate/Sandwich technique
- Core build-up where at least 50% of coronal tooth structure is remaining for support

Generally coronal tooth structure that is exposed to high stress factors, i.e. cusps, should not be restored with any glass ionomer type restorative materials.

Below is a reference guide for selecting the best 3M ESPE glass ionomer material for use and indications.

Indications									
	Small Class I	Class III	Class V	Minimal Invasive Dentistry (MID)	Primary Teeth	Base Under Composite	Temporary Treatment	Core Build-up	Delivery
RESIN MODIFIED									
Ketac™ Nano	●	●	●	●	●	●	●	●	
Photac™ Fil	●	●	●	●	●		●		
Vitremer™	●	●	●	●	●	●	●	●	
CONVENTIONAL									
Ketac™ Molar Quick	●		●	●	●	●	●	●	
Ketac™ Molar	●		●	●	●	●	●	●	
Ketac™ Fil Plus	●	●	●	●	●			●	
METAL REINFORCED									
Ketac™ Silver	●		●		●		●	●	

Helpful Hints

Shade Selection

Ketac™ Nano Light Curing Glass Ionomer Restorative shades are based on the Filtek™ Supreme Plus Universal Restorative System. There is a selection of eight different shades; A1, A2, A3, A3.5, A4, B2, C2, and Blue. As with composite restorative systems, shade selection for an esthetic restoration should be made with teeth fully wet. For core builds, while any shade could be used, a contrasting color to tooth structure such as the blue shade is sometimes preferred by dentists.

Priming

Ketac™ Nano Primer is quite fluid so it should be dispensed into a well rather than onto a pad. It is applied to both enamel and dentinal surfaces for 15 seconds. Keep the prepared tooth surfaces wet with the primer for the full application time. Scrubbing the surface with the primer is not necessary. The primed surface will appear shiny after drying and light curing.

Using the Ketac Nano primer as instructed is critical to achieving adhesion of Ketac Nano restorative to tooth structure. Primer use must not be eliminated from the procedure.

Dispensing

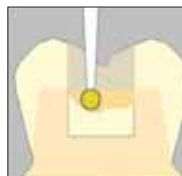
Ketac Nano restorative was designed to be dispensed and mixed with equal volumes of each paste in a ratio of 1.3/1.0. Dispensing two clicks from the Clicker™ Dispenser should provide an adequate amount of material for most restorative filling applications. This is a guideline, and the user will need to determine appropriate amounts for specific applications as they become familiar with the product. In the unlikely event the dispensed pastes appear to be of uneven volume, the dose should be discarded. When replacing the cap be sure an audible “click” is heard to assure a tight fit.

Mixing

The user must mix both pastes together for 20 seconds using a cement spatula. Paste may appear homogenous in less than 20 seconds, however less than 20 seconds of mixing may effect some of the features and benefits of Ketac™ Nano Light Curing Glass Ionomer restorative, such as esthetics.

Placement

- We recommend placement of Ketac Nano restorative with a syringe system. Most of our evaluators reporting on their experiences with the material found this placement technique to be acceptable.
- Wetting the dental instruments used for shaping and contouring with Ketac™ Nano Primer may prevent the glass ionomer from adhering to them. Another option is to use the fiber tip primer applicator when manipulating the material in the prep.
- Ketac Nano restorative becomes relatively firm shortly after placement which can aid in shaping the anatomy. However, do not exceed the 3 minute working time. Doing so may result in deminished esthetics.
- Like most resin modified glass ionomers, Ketac Nano restorative cannot be placed in bulk, layering of $\leq 2\text{mm}$ is required.



Curing

Ketac™ Nano restorative should be placed in 2mm increments or less, and light cured after each increment. An LED curing light will cure all shades with a 20 second light exposure. Halogen lights are the same with the exception of the darker A3.5 and A4 shades which require a 30 second exposure.

Finishing

As with any finishing and polishing procedure with glass ionomer restorative materials it is recommended that the surface be kept moist. Ketac Nano restorative can be polished with conventional finishing and polishing instruments such as a diamond impregnated rubberized polishing system. A glaze such as Vitremer™ Finishing Gloss may also be applied after polishing if desired.

Instructions for Use

Indications

Ketac Nano Light Curing Glass Ionomer Restorative system is indicated for:

- Primary teeth restorations
- Small Class I restorations
- Class III and V restorations
- Transitional restorations
- Filling defects and undercuts
- Laminate/Sandwich technique
- Core build-ups where at least 50% of coronal tooth structure is remaining for support

Generally coronal tooth structure that is exposed to high stress factors, i.e. cusps, should not be restored with any glass ionomer type restorative materials.

Contraindications

The Ketac™ Nano Light Curing Glass Ionomer Restorative system **is not recommended for direct pulp capping**. Cover areas in close proximity of a pulpal exposure with a small amount of hard setting calcium hydroxide material (e.g. Alkaliner™), or a resin modified glass ionomer liner (e.g. Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base) both manufactured by 3M ESPE. Do not use these products for capping an exposed pulp chamber.

Precautionary Information for Patients

Avoid use of these products in patients with known acrylate allergies. This product contains substances that may cause an allergic reaction by skin contact in certain individuals. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel

These products contain substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

Instructions for Use

1. Shade selection. For esthetic restorations, select the desired shade using the Ketac™ Nano Light Curing Glass Ionomer Restorative shade guide.

2. Cavity Preparation. Remove caries. Rinse and slightly dry cavity, do not desiccate. Ketac Nano restorative is not recommended for direct pulp capping. Apply a liner if pulp tissue is near exposure conditions.

3. Primer

Ketac™ Nano Glass Ionomer Primer **must** be applied to the preparation before restoring tooth with Ketac Nano restorative. Core buildups with multiple missing cusps may require placement of pins for retention. For core buildups with pins, apply primer to pins as well.

- a. Dispense the Ketac Nano primer into a well.
- b. Using a fiber tip, apply primer for 15 seconds to prepared semi-dry enamel and dentin surfaces. Replenish primer as needed to assure surfaces are kept wet with primer for the recommended application time.
- c. Dry the primer using an air syringe for 10 seconds. **Do not rinse.** After drying, the primed surfaces will remain shiny in appearance.
- d. Light cure the primed surfaces for 10 seconds using a 3M ESPE curing unit or other dental visible light curing unit of comparable intensity.
- e. The light cured surfaces will appear shiny.

Note: By adequately drying and separately light curing the primer, maximum adhesion of the glass ionomer to tooth structure is obtained. The primer is light sensitive and contains photoinitiators and water. Minimize ambient light exposure and evaporation by dispensing just prior to use and replacing vial cap immediately after dispensing.

4. Dispensing

Clicker™ Dispenser

Note: Dispense and mix Ketac™ Nano Light Curing Glass Ionomer Restorative immediately prior to use to avoid water evaporation and drying out of the pastes. This product was designed to be dispensed and mixed with equal volumes of each paste. In the unlikely event the dispensed pastes appear to be of uneven volume, the dose should be discarded.

- a. Remove cap from the Clicker dispenser by holding down the cap lever and sliding the cap off of the dispenser.
- b. Dispense a small amount of material onto a mix pad to ensure even dispensing of both pastes. Discard this material.
- c. Fully depress clicker lever to dispense Ketac Nano restorative onto a mix pad. Allow paste to fully extrude for 2-3 seconds, then release lever. Repeat dispensing process for additional material, most restorations will require approximately 2 clicks. The paste is automatically dispensed in equal volumes. The actual weight ratio dispensed is (1.3/1.0).
- d. Wipe the dispenser tips clean with gauze to prevent cross contamination of the two pastes.
- e. Replace cap by sliding onto dispenser until securely latched and an audible "click" is heard.

5. Mixing

- a. Using a plastic or metal cement spatula, mix the pastes together for 20 seconds until a uniform color is achieved. Avoid the incorporation of air bubbles.
- b. Place material into preparation using conventional dental instruments, or back load a delivery tip by pressing it down over the mixed glass ionomer, insert piston flush with the back of the tip and place tip into a 3M ESPE capsule dispenser or similar device.

6. Placement

In a semi-dry to dry field incrementally syringe or place material in a depth of 2mm or less. Wetting dental instruments used for shaping and contouring with Ketac Nano Primer can prevent glass ionomer restorative from adhering to them. Working time is 3 minutes from start of mix at room temperature of 23°C (73°F).

- a. Cavities. Place or syringe the mixed Ketac Nano restorative into the cavity keeping the syringe tip immersed in the material to minimize air entrapment. Material will become firmer, shortly after placement. Shape and contour the restoration using an appropriate placement instrument.
- b. Core buildups. Place or syringe the Ketac Nano restorative into undercut areas, around pins, around posts, then fill the preparation in increments of 2mm or less.
Note: Once cured the prepared Ketac Nano core buildup is compatible with conventional impressioning materials. The core build up should be kept wet with saliva or lubricated to prevent bonding to chemical cure provisional. The glass ionomer core build up will not bond with temporary cements.
- c. Laminate/Sandwich Technique. Use when cavity design allows for a minimum composite restorative thickness of 2mm on occlusal surface. Syringe material into the preparation if margins are located partially in dentin or aprismatic enamel as, for example, in deep Class II cavities.

Syringe material in prepared cavity extending the glass ionomer restorative base no further than apical to the proximal contact point.

Note: After light curing refine by removing excess Ketac Nano primer and Ketac Nano restorative base material from enamel margins and cavity walls to be bonded subsequently with the adhesive/composite system.

7. Curing

Ketac Nano restorative will cure only by exposure to visible light. **The maximum depth of material for light curing should not exceed 2 mm.** Light cure the Ketac Nano restorative by exposing its entire surface area to a 3M ESPE visible light curing unit or other dental light curing unit of comparable intensity according to the chart .

3M ESPE Light	mW/cm ²	Seconds	Shades
Elipar™ FreeLight 2 LED	≥1000	20	All
Elipar™ 2500 Halogen	≥450	20	A1, A2 A3, B2, C2, Blue
Elipar™ 2500 Halogen	≥450	30	A3.5, A4

8. Finishing

Immediately after curing, the Ketac Nano restoration can be contoured and polished using conventional finishing and polishing instruments, (e.g. Sof-Lex™), under moist conditions.

9. Storage and Use

1. Shelf life at room temperature is 24 months. See outer package for expiry date.
2. Recommended storage 2-27 C (36-80 F)
3. The Ketac Nano system is to be used at room temperature of approximately 21-24°C (70-75°F). If material has been refrigerated prior to use allow time to bring to room temperature.
4. Primer and paste are light sensitive materials. Protect them from ambient light exposure by dispensing just prior to use and replacing caps immediately after dispensing.
5. Clicker disinfection. Disinfect the capped Clicker using an intermediate level disinfection process (liquid contact) as recommended by the Center for Disease Control and endorsed by the American Dental Association, Guidelines for Infection Control in Dental Health-Care Settings –2003 (Vol. 52; No. RR-17), Center for Disease Control and Prevention.

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Step-by-Step Technique Guides

Clicker Technique Guide

3M ESPE

CLICKER DISPENSER OPERATION



Ketac Nano Light Curing Restorative Technique Guide

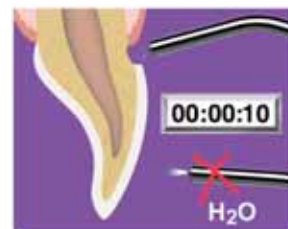
3M ESPE

Ketac™ Nano

Light Curing Glass Ionomer Restorative

Indications:

- Primary teeth restorations
- Small Class I restorations
- Class III and V restorations
- Transitional restorations
- Filling defects and undercuts
- Laminate/Sandwich technique
- Core build-ups



Ketac Nano Technique Guide cont.

Option A



Option B



Questions and Answers

Q. How many applications are in the Clicker™?

- A. This will vary with the amount used for each procedure. Each Ketac™ Nano Light Curing Glass Ionomer Restorative Clicker contains 12g of paste and will deliver approximately 80 clicks. The amount of material delivered from a glass ionomer unit dose triturator capsule is about 300-350mg, two clicks of Ketac™ Molar Glass Ionomer Filling Material is approximately 250-300mg.

Q. How many applications are there in a vial of Ketac™ Primer?

- A. There are approximately 160 drops per bottle of primer.

Q. Ketac Nano restorative is a resin modified glass ionomer with the acid base setting reaction. Why can't I do a bulk placement since any material not light activated will eventually set anyway?

- A. Ketac Nano restorative is a resin modified glass ionomer that does exhibit a slowed down GI setting reaction. Ketac Nano restorative contains reactive methacrylate monomers, which must be cured in 2mm or less increments to minimize residual unreacted monomers in the lower levels of the restoration and because there is no "redox" reaction that allows for continuing polymerization in the absence of light activation. Also, not properly light curing can have an effect on the physical properties.

Q. Could I use the Vitremer™ Primer with Ketac Nano restorative?

- A. No. There are similarities between the two primers, however Vitremer Primer should not be used with Ketac Nano Restorative. Use only Ketac Nano primer for conditioning the surface of the restoration.

Q. Does Ketac Nano restorative bond to itself?

- A. Yes, adhesion studies indicate that additional Ketac Nano restorative can be added to cured Ketac Nano Restorative.

Q. I've noticed shortly after placement Ketac Nano restorative starts to firm up or set. With some GI's they caution against manipulating the material at this point and disrupting the GI reaction consequently reducing some of its physical properties. Is this also true for Ketac Nano Restorative?

- A. The major contributor to the "firming-up" is the physical interaction between the components of the two pastes. This interaction evolves with time but does not lead to a significant setting reaction, or any decrease in the properties when the pastes are manipulated within the specified **3 minute working time**.

Q. Why do I need to use a primer?

- A. One of the fundamental rules in obtaining a good adhesive bond is to bring together two surfaces that are equivalent in their surface energies. All glass ionomer restorative materials, with the exception of 3M ESPE Photac™ Fil, require a pre-treatment step prior to placing the GI restorative material. For the Ketac Nano restorative the acidic, low viscosity Ketac Nano primer modifies the smear layer and wets the tooth structure so as to provide a constant surface which is ideally receptive to the glass ionomer mix. The acidic polymer of the primer has a strong inherent attraction for the dentin and enamel surfaces. Photocuring the primer crosslinks the methacrylate groups of the polymer and provides an integral surface that is ready for the placement of the ionomer mix.

Q. How does Ketac™ Nano Light Cure Glass Ionomer Restorative handle?

- A. The mixed pastes are thick and putty like and will become slightly firmer shortly after mixing. Users of resin modified glass ionomer will find it handles about the same as their current materials. Compared to some of the conventional glass ionomer powder/liquid hand mix materials, Ketac Nano Restorative may be perceived as somewhat softer depending on the powder/liquid ratio used. To aid in placement some doctors find it helpful to moisten placement instruments with the Ketac™ Nano Primer or wait until the material achieves a slightly firmer, non-sticky consistency

Warranty

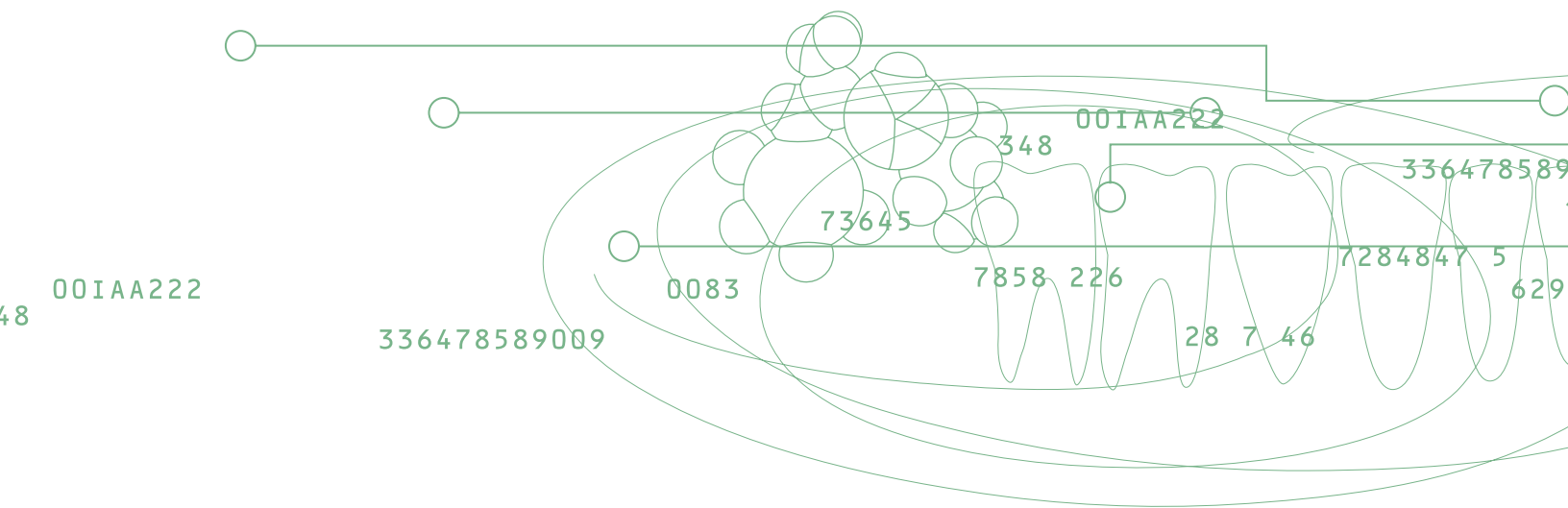
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