



3M

Filtek™

**One
Bulk Fill Restorative**

Technical Product Profile

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Introduction

Since the introduction of light curable composites, dentists have been required to place the material in increments. These composites require light (in the proper wavelength) to excite a photo-initiator, which begins the polymerization process. If the light penetration is insufficient, poor initiation of this reaction can result, which can lead to under-cured or uncured material. The depth of cure of a composite is determined by the monomers, initiators, fillers and shade/opacity of the material. Additionally, the effectiveness of the light is influenced by many factors, including the wavelength, light intensity, distance from the light source and exposure time. Dentists use incremental placement techniques for a variety of reasons in addition to the cure depth of the composite. Incremental placement is used to manage the shrinkage and corresponding shrinkage stress resulting from the polymerization reaction. Incremental placement allows for more precise manipulation of the restorative to ensure adaptation, particularly at the cavosurface. It reduces the possibility of voids and aids in forming contacts and sculpting the occlusal surface prior to cure. Managing the shrinkage stress and ensuring proper adaptation may reduce the incidence of post-operative sensitivity. Additionally, incremental placement readily lends itself to creating multi-shade restorations.

On the other hand, incremental placement is considered time-consuming and tedious, especially in posterior teeth. Increments may increase the potential of voids to form between composite layers, and composites must be placed in a dry field. The risk of contamination leading to a compromised restoration is adversely impacted by the time it takes to place, adapt and cure each increment.

In an effort to provide materials that address the challenges of incremental placement, and also to provide an alternative material to amalgam, packables were launched in the late 1990s. These materials had a high viscosity and contained a high filler load. Manufacturers claimed the handling was amalgam-like and the material stiffness aided in forming contacts. In addition, many of the packables were reported to have the capability of being bulk placed, i.e., to be placed and cured in 4–5mm increments. However, the high viscosity of these composites made adaptation to the cavosurface more challenging.^{1,2} The actual depth of cure of these materials was found to be less than claimed.³ Even if the adequacy of cure was acceptable, the clinical ramifications of shrinkage stress became more prominent with thicker (4–5mm) layers. Studies have shown that many of these materials still had high shrinkage and polymerization stress.

The field of materials science has made remarkable advancements with composite filling materials used for direct procedures, which offer dentists solutions to many of the issues they see every day. It is widely understood in the scientific and dental communities that bulk filling a restoration increases stresses on the tooth and can decrease bond strength. However, with the capabilities of materials currently available to manufacturers, it is possible to create materials/products that offer lower polymerization shrinkage stress when compared to incrementally placed composite.

The current materials available for bulk filling are gaining acceptance in the dental clinic, and market share data reflects the growing use of these materials. Scientific advancements continue to be made in order to optimize the bulk fill materials to manage stress, ensure or increase the depth of cure and to enhance the esthetics. Esthetics, in particular, have been a primary focus for improvement due to the fact that most materials require more translucency than conventional composites in order to manage the depth of cure for bulk filling.

Product Description

3M™ Filtek™ One Bulk Fill Restorative is a visible-light activated, restorative composite optimized to create fast and easy restorations. This material provides excellent strength and low wear for durability and improved esthetics. The material can be placed and cured up to 5 mm deep, enabled by a stress-relieving resin system and optimized optical properties. Filtek One Bulk Fill Restorative serves to enhance the 3M lineup of restorative materials by improving the esthetic properties of a bulk fill material to allow for broader use in both posterior and anterior restorations.

Product Features

- Fast and easy one-step placement
- Increased opacity for improved esthetics
- Stress relief to enable up to 5mm depth of cure
- Excellent adaptation
- Excellent handling and sculptability
- True nanotechnology for superior wear resistance and excellent polish retention
- High radiopacity
- Unique capsule tip design for easier access to deep cavities
- Available in 5 shades: A1, A2, A3, B1, C2
- Packaged in 0.2 gram capsules and 4.0 gram syringes

Indications for Use

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel and temporaries

Composition

The fillers are a combination of a non-agglomerated/non-aggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to 11nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20nm silica and 4 to 11nm zirconia particles) and a ytterbium trifluoride filler consisting of agglomerate 100nm particles. The inorganic filler loading is about 76.5% by weight (58.5% by volume). 3M™ Filtek™ One Bulk Fill Restorative contains AFM (dynamic stress-relieving monomer), AUDMA, UDMA and 1, 12-dodecane-DMA. 3M™ Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as those manufactured by 3M, which permanently bonds the restoration to the tooth structure. Filtek One Bulk Fill Restorative is packaged in traditional syringes and single-dose capsules.

Shades

Filtek One Bulk Fill Restorative material is available in 5 shades:
A1, A2, A3, B1 and C2.

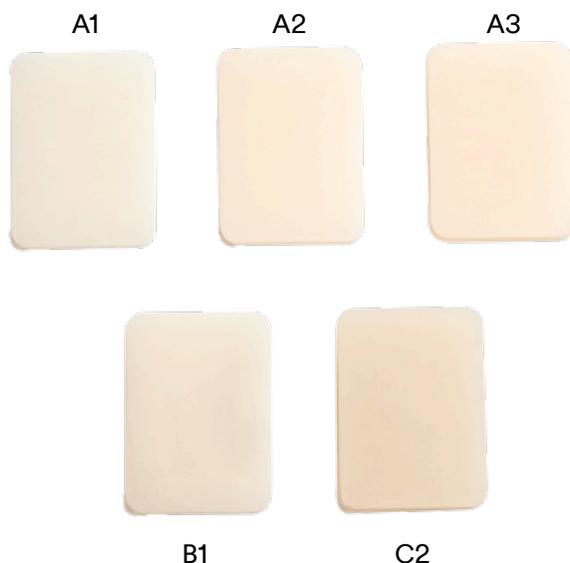


Figure 1: Source: 3M internal data

Background

Resin System

The primary aim of the resin development effort was to design a material that would allow a practitioner to place and cure a 5mm deep restoration up to occlusion. In order to accomplish this task, many aspects of the resin system needed to be considered. One of the primary considerations in designing this resin system was the ability to relieve the amount of shrinkage stress upon light curing. Additionally, because this is a bulk fill material, the depth of cure of the material was a key property considered during development. Since this material was designed to be filled up to occlusion, attaining high wear resistance was a central effort. Another key factor that had to be considered for a material that will be filled in bulk was optimized handling and enhanced adaptation to the cavity preparation.

Methacrylate composites have an inherent tendency to shrink during polymerization and can shrink to varying degrees depending on the monomers being used. 3M™ Filtek™ One Bulk Fill Restorative contains two novel methacrylate monomers that, in combination, act to lower polymerization stress. One monomer, a high-molecular-weight aromatic urethane dimethacrylate (AUDMA) (Figure 2), decreases the number of reactive groups in the resin. This helps to moderate the volumetric shrinkage as well as the stiffness of the developing and final polymer matrix—both of which contribute to the development of polymerization stress.

AUDMA

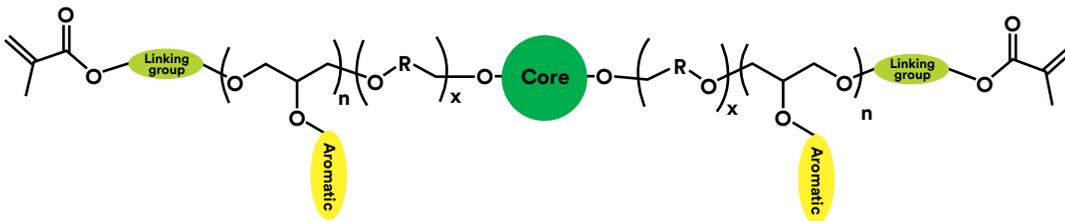


Figure 2: AUDMA structure. Source: 3M internal data

The second unique methacrylate represents a class of compounds called addition fragmentation monomers (AFM) (Figure 3). During polymerization, AFM reacts into the developing polymer as with any methacrylate, including the formation of cross-links between adjacent polymer chains. AFM contains a third reactive site that cleaves through a fragmentation process during polymerization. This process provides a mechanism for the relaxation of the developing network and subsequent stress relief. The fragments, however, still retain the capability to react with each other or with other reactive sites of the developing polymer. In this manner, stress relief is possible while maintaining the physical properties of the polymer.

AFM



Figure 3: AFM structure. Source: 3M internal data

DDDMA (1, 12-Dodecanediol dimethacrylate) (Figure 4) has a hydrophobic backbone that increases its molecular mobility and compatibility with nonpolar resins and aids in adjusting viscosity.

DDDMA

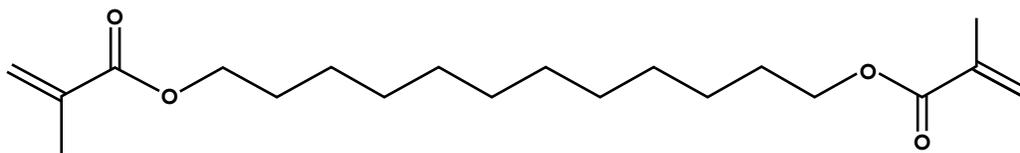


Figure 4: DDDMA structure. Source: 3M internal data

UDMA (urethane dimethacrylate) (Figure 5) is a relatively low-viscosity, high-molecular-weight monomer.

UDMA

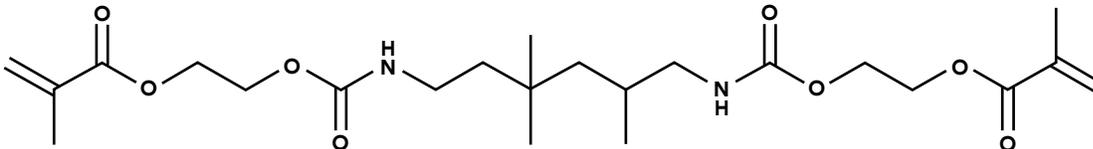


Figure 5: UDMA structure. Source: 3M internal data

Additionally, the higher molecular weight effectively reduces the shrinkage while still creating a tough, highly cross-linked network.

By modifying the proportions of these high-molecular-weight monomers, a resin system with the properties of a sculptable bulk fill material was developed. The resin system also produces polymerization shrinkage stress relief and a depth of cure of 5 mm.

Fillers

The fillers included in 3M™ Filtek™ One Bulk Fill Restorative were designed to maximize strength, wear resistance and radiopacity while minimizing shrinkage and maintaining good handling. The nanofiller system in Filtek One Bulk Fill Restorative is the same system found in 3M™ Filtek™ Bulk Fill Posterior Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative. As with Filtek Bulk Fill Posterior Restorative, Filtek One Bulk Fill Restorative also contains agglomerate 100nm ytterbium trifluoride (YbF₃) particles for increased radiopacity. The remaining fillers are a combination of a non-agglomerated/non-aggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to 11nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20nm silica and 4 to 11nm zirconia particles), making the total inorganic filler loading approximately 76.5% by weight (58.4% by volume).

Smart Contrast Ratio Management

Smart Contrast Ratio Management is a concept where, by managing the interaction and refractive index between the resin and the filler, the opacity of the composite can be increased without sacrificing the depth of cure. Contrast ratio is the measurement of the degree of opacity or translucency. The higher the contrast ratio, the more opaque the material will be.

3M™ Filtek™ One Bulk Fill Restorative utilizes novel proprietary 3M nanotechnology to alter the opacity of the composite material during cure. The ability to have an uncured paste that is more translucent than that of the final cured paste allows light to penetrate deeply into the restorative material, activating the cure chemistry throughout the composite, allowing the depth of cure to be thus achieved. The material, however, changes in contrast ratio during cure due to a scientifically designed in-situ creation of a refractive index mismatch, which also allows the cured material to have a greater final opacity for improved esthetics of the restoration.

Figure 6 shows the opacity difference between cured Filtek One Bulk Fill Restorative and Filtek Bulk Fill Posterior Restorative. The more translucent Filtek Bulk Fill Posterior Restorative does not block out the underlying black and white lines and has more show through. The cured Filtek One Bulk Fill Restorative is more opaque and can mask the underlying markings much better. The graph shows the actual contrast ratio measurements between the two composites; the higher contrast ratio of Filtek One Bulk Fill Restorative results in the higher opacity that is seen in the disc images. Additionally, the graph also shows a band or range of contrast ratios (opacities) for some typical universal composites. The contrast ratio or opacity of Filtek One Bulk Fill Restorative falls within the range of opacities for those universal composites.

Contrast Ratio

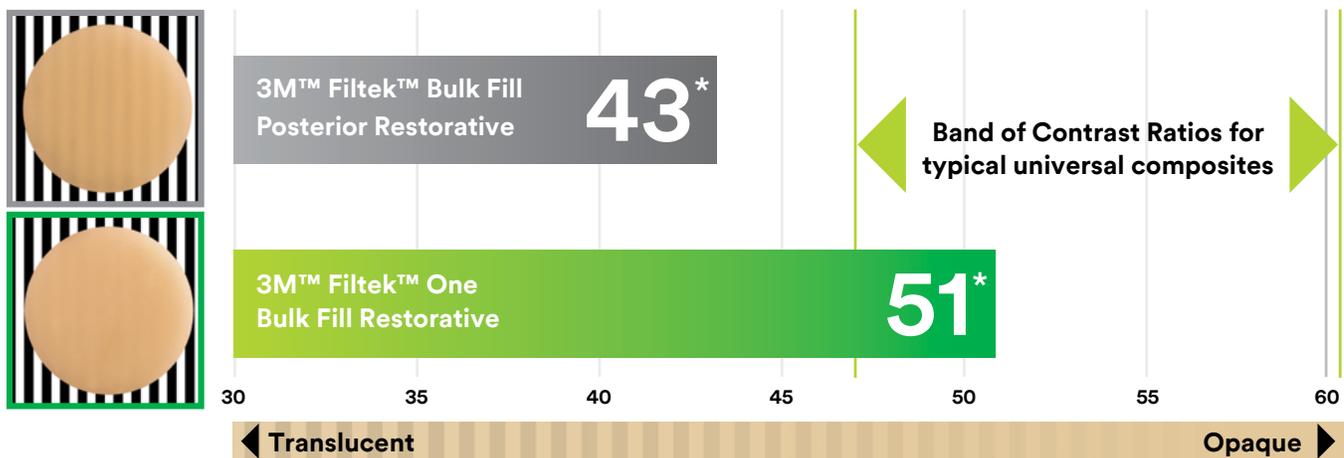


Figure 6: Contrast ratio measurements for 3M™ Filtek™ One Bulk Fill Restorative, 3M™ Filtek™ Bulk Fill Posterior Restorative and a range of typical universal composites. Source: 3M internal data

Physical Properties

Contrast Ratio/Opacity

As mentioned, contrast ratio is the actual measurement of a material's opacity or translucency. The higher the contrast ratio, the higher the opacity. 3M™ Filtek™ One Bulk Fill Restorative has a higher contrast ratio and opacity than 3M™ Filtek™ Bulk Fill Posterior Restorative, Venus® Bulk Fill, Tetric EvoCeram® Bulk Fill and SureFil® SDR® flow+ Bulk Fill Flowable (Figure 7).

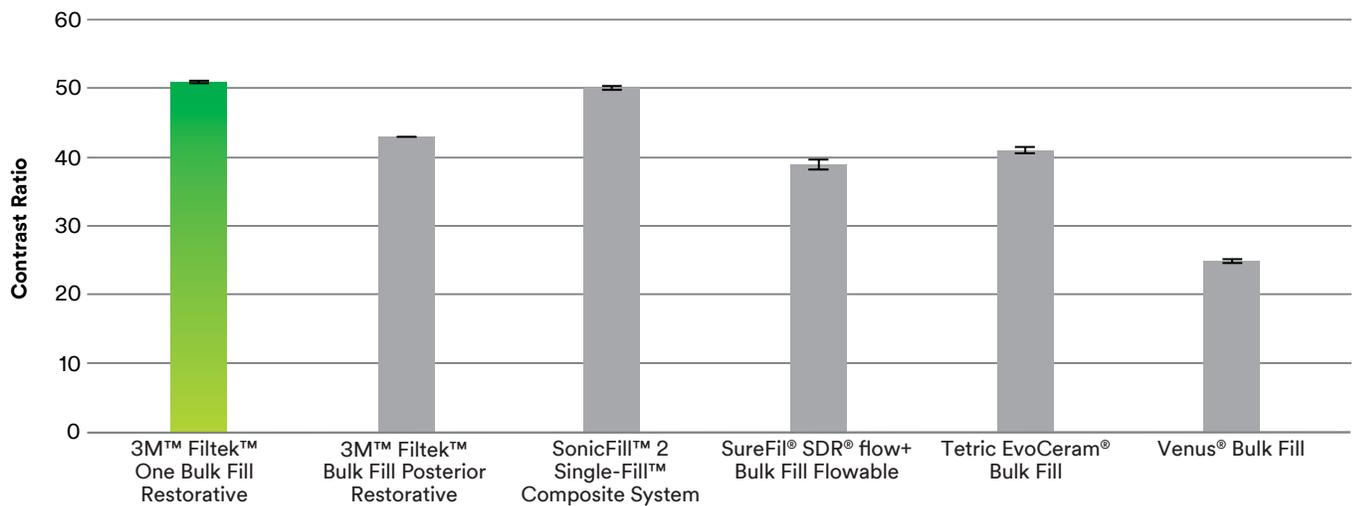


Figure 7: Comparison of contrast ratio/opacity for common bulk fill materials. Source: 3M internal data

4mm Depth of Cure

Several methods are available for characterizing the extent of polymerization of light-cured dental composite filling materials. One is the “scrape-back” method, which is the basis of the depth of cure method described by ISO 4049:2009. In this ISO standard, the uncured composite is placed in a cylindrical-shaped stainless steel mold and light cured from one end of the mold. The composite is immediately extracted from the mold and the unpolymerized or low-polymerized composite is scraped off the end farthest from the light. The length of the remaining “cured” composite is measured and divided by a factor of 2. This length is typically rounded to the closest integer value and claimed as the depth of cure. This follows from the ISO 4049 specification, which allows a claimed depth of cure 0.5 mm greater than half the scrape-back measurement. It has been shown that the extent of polymerization throughout this length decreases from the end closest to the light (where light intensity was greatest) to the end where the uncured material was scraped off.⁴ It was also shown that the extent of polymerization at half the scraped-back length is approximately 90% of the maximum polymerization.⁴ All shades of 3M™ Filtek™ One Bulk Fill Restorative meet the 4mm depth of cure requirements. Depths of cure for Filtek One Bulk Fill Restorative and 3M™ Filtek™ Bulk Fill Posterior Restorative measured using the ISO 4049 standard and a 20-second cure with the 3M™ Elipar™ DeepCure-S Curing Light using its 10mm light guide are shown below (Figure 8).

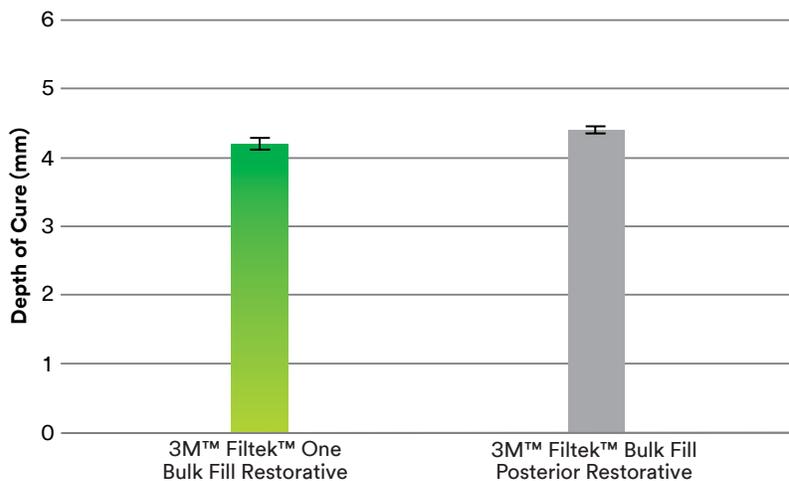


Figure 8: ISO 4049 Depth of Cure – 3M™ Filtek™ One Bulk Fill Restorative and 3M™ Filtek™ Bulk Fill Posterior Restorative. 20-second exposure, 3M™ Elipar™ DeepCure-S LED Curing Light. Source: 3M internal data

Another common method for assessing extent of polymerization is microhardness testing, which has been shown to correlate with the extent of polymerization.⁵ As in the ISO method, it is typical to place the uncured composite in some type of mold and light cure from one end of the mold. This sample is then extracted and the hardness is measured along its length. Rather than reporting the actual hardness value measured, it is more meaningful to represent the hardness at any given point within the sample as a percentage of the maximum hardness attained. It has been shown with a variety of different composites that 80% of the maximum hardness was associated with 90% of the maximum polymerization.⁶

The clinical significance of both tests as described above is not known. In other words, the extent of polymerization that is needed for a durable restoration has not been determined. Some investigators have suggested 80% of maximum microhardness (equivalent to half the scraped-back length as defined by the ISO standard) as a minimum threshold.^{4,5} This recommended threshold, however, is not based on clinical studies or laboratory models involving extracted teeth. Recent laboratory studies involving extracted human teeth have suggested a lower limit of polymerization at 73% of maximum microhardness or 80% of maximum polymerization.⁶

5mm Depth of Cure (ex vivo tooth model)

The depth of cure of 3M™ Filtek™ Bulk Fill Posterior Restorative was investigated in Class II slot preparations in extracted molars at the Oregon Health & Science University via a 3-surface curing protocol and reported previously. Similar experimentation was conducted for 3M™ Filtek™ One Bulk Fill Restorative using the OHSU protocol. The experimental tooth was placed in a simulated arch between two adjacent teeth. The depth of the preparation was 5 mm to the gingival floor with a 3.5 mm width and 2 mm depth. (Figure 9).

1. Restoration placement



- Class II slot preparation in molar tooth, not tapered
- Metal matrix

2. Extract restoration



3. Cut restoration through middle in the mesial-distal direction



- ### 4. Measure Knoop Microhardness
- along band side, b) down middle, c) along axial side of tooth in 1mm increments starting 0.1 mm from the top and 0.5 mm within the band and tooth side surfaces

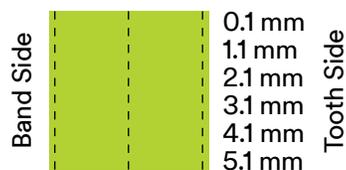


Figure 9: Representation of slot preparations. Source: Oregon Health & Science University

The preparation was lightly lubricated with Vaseline, a circumferential metal Toffelmire matrix band was applied and the restorations using 3M™ Filtek™ One Bulk Fill Restorative (Shade A3) were placed. One set of restorations was cured with the 3M™ Elipar™ FreeLight 2 Curing Light to represent the low end of the light output range (< 1000 mw/cm²) that allows for a 10-second-per-surface three-sided curing technique: 10-second occlusal cure followed by removing the matrix band and curing 10 seconds each from the buccal and lingual surfaces. The second set of restorations was cured with a 3M™ Elipar™ TriLight Curing Light to represent the low end of the light output range (550–1000 mw/cm²) that allows for a 20-second-per-surface three-sided curing technique: 20-second occlusal cure followed by removing the matrix band and curing 20 seconds each from the buccal and lingual surfaces.

After curing, the composite restoration was removed from the tooth preparation, embedded in epoxy and sectioned through the middle in a mesial-distal orientation. The Knoop hardness was determined in 1mm increments starting 0.1 mm below the occlusal surface. The last Knoop hardness reading made 0.1 mm above (occlusal) to the gingival floor of the restoration. The Knoop hardness measurements were made at each depth and averaged for the value at each depth of each specimen. Three series of hardness measurements were obtained per section.

The lower threshold of acceptable hardness is determined by calculating the 80% hardness value for the maximum hardness of the sample at 0mm depth. Figures 10 and 11 show that Filtek One Bulk Fill Restorative reaches sufficient hardness at 5mm depth for both the higher and lower light intensity light conditions after following their appropriate multi-sided curing protocol.

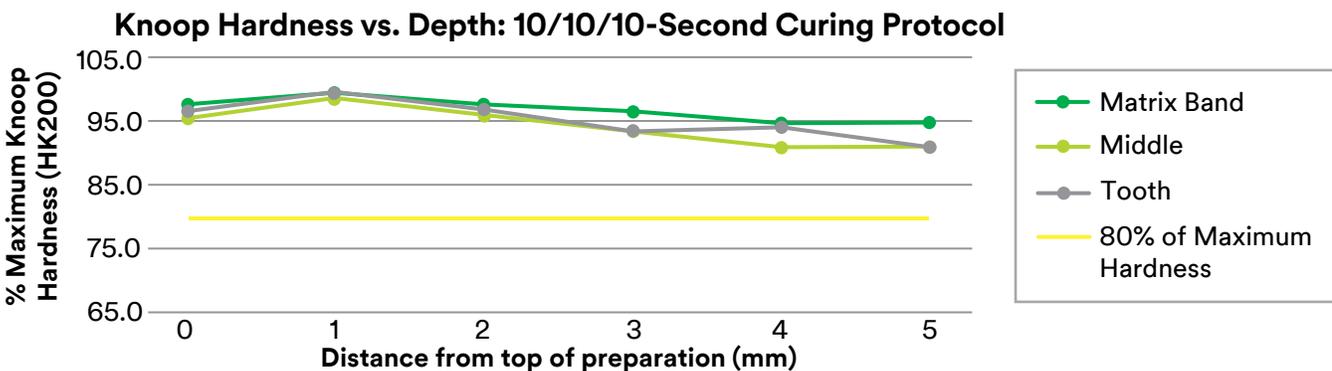


Figure 10: Hardness versus depth utilizing the 10-second occlusal/10-second buccal/10-second lingual curing protocol. Source: 3M internal data

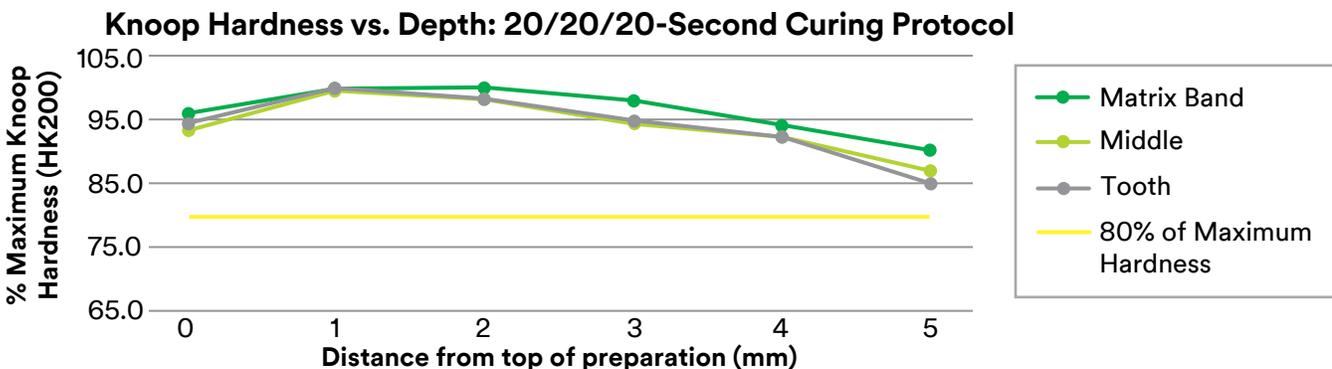


Figure 11: Hardness versus depth utilizing the 20-second occlusal/20-second buccal/20-second lingual curing protocol. Source: 3M internal data

Polymerization Shrinkage

A method for determining polymerization shrinkage was described by Watts and Cash.⁷ In this method, a disc-shaped test specimen and uncured paste is sandwiched between two glass plates and light cured through the lower rigid plate. The flexible upper plate is deflected during the polymerization of the test specimen. The less the flexible plate bends, the lower the shrinkage. Deflection is measured and recorded as a function of time. Although this process actually measures linear shrinkage, volumetric shrinkage was closely approximated due to the fact that the dimensional changes were limited to the thickness dimension. The lower the value, the less the shrinkage. 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Posterior Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative and has lower polymerization shrinkage than Venus® Bulk Fill, SureFil® SDR® flow+ Bulk Fill Flowable, Herculite™ Ultra Universal Nanohybrid Dental Composite and TPH Spectra® Universal Composite Restorative (HV) High Viscosity (Figures 12, 13).

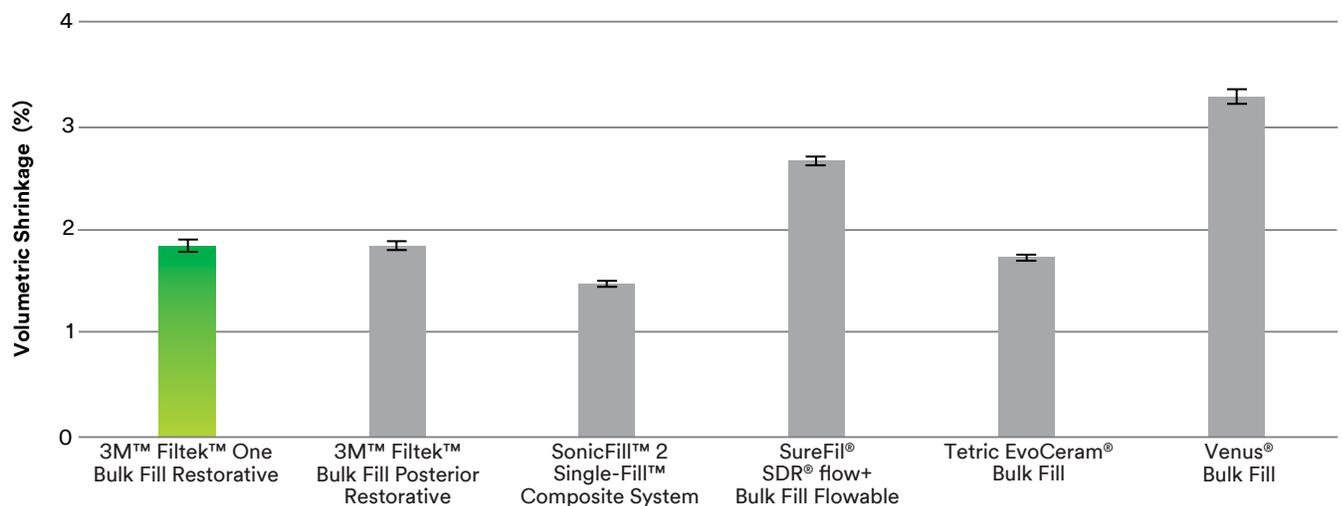


Figure 12: Polymerization shrinkage of common bulk fill composites. Source: 3M internal data

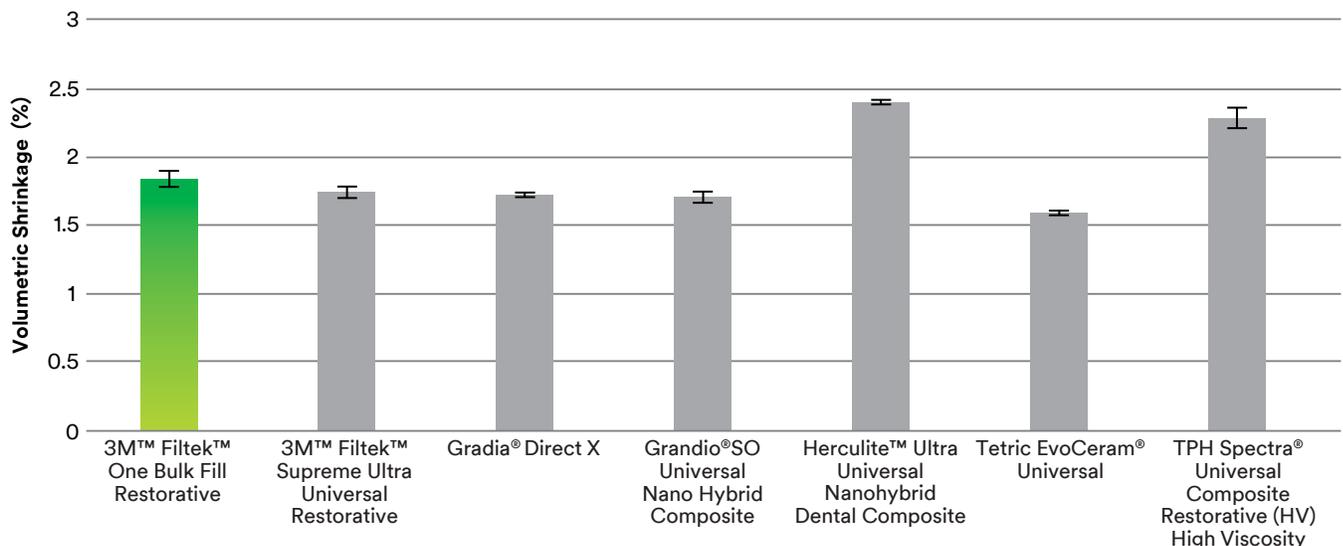


Figure 13: Polymerization shrinkage of common incrementally placed universal composites. Source: 3M internal data

Polymerization Stress/Cusp Deflection

Shrinkage can cause stress in the tooth, the bonding layer and within the composite. Stress can be a result of the combination of shrinkage and modulus. For materials with similar shrinkage, the material with the higher modulus (or stiffness) will produce greater stress. Conversely, for materials with similar moduli, the material that exhibits the highest shrinkage will produce greater stress. Cusp deflection is a 3M test method that was designed to provide a relative estimate of polymerization shrinkage stress resulting from placing and curing a dental composite in a 4×4mm open-ended cavity. The cavity dimension roughly simulates a large cavity preparation (e.g., mesial – occlusal – distal (MOD) preparation). The surface of the aluminum cavity is sandblasted and silane treated and a dental adhesive is applied. A composite is then placed in the aluminum cavity to a final depth of 4 mm, either incrementally or bulk filled, and cured with a dental curing light (e.g., one 4mm deep application of bulk fill composite or two 2mm deep increments of incremental composite, each placed and light cured). A linear variable displacement transducer is used to measure the displacement of the aluminum cavity wall due to polymerization shrinkage stress. Aluminum was selected as the block material because it has a modulus similar to human enamel. A similar cusp deflection method using an aluminum block has been described in the literature.⁸ 3M™ Filtek™ One Bulk Fill Restorative has similar polymerization stress when placed in bulk compared to many of the universal materials that are placed in increments (Figure 15).

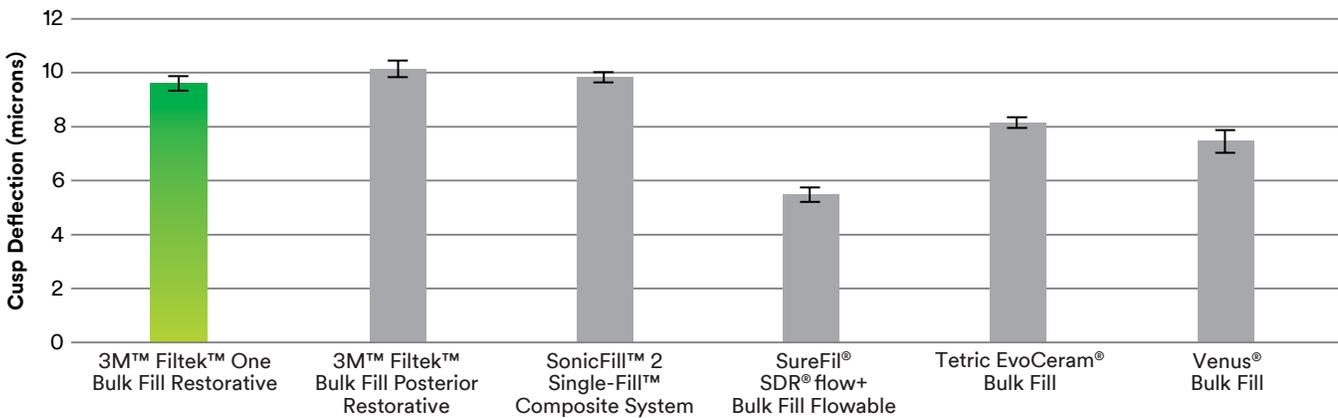


Figure 14: Cusp deflection of common bulk fill composites. Source: 3M internal data

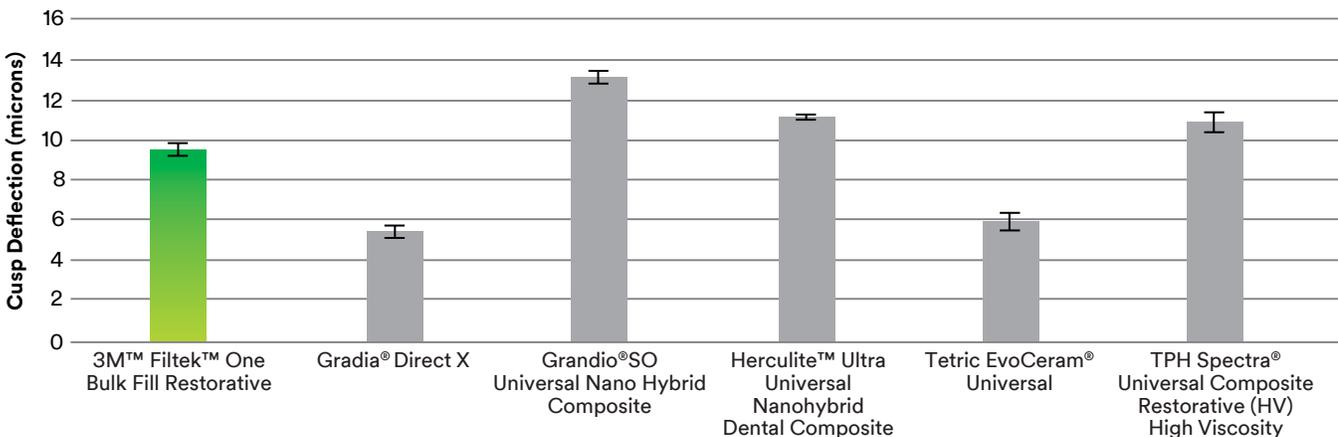


Figure 15: Cusp deflection of common incrementally placed universal composites. Source: 3M internal data

Flexural Modulus

Flexural modulus is a method of defining a material’s stiffness. A high modulus indicates a rigid material. The flexural modulus is determined by applying a load to a material specimen that is supported at each end, measuring how much the specimen deflects. 3M™ Filtek™ One Bulk Fill Restorative has equivalent flexural modulus to 3M™ Filtek™ Bulk Fill Posterior Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative (Figures 16, 17).

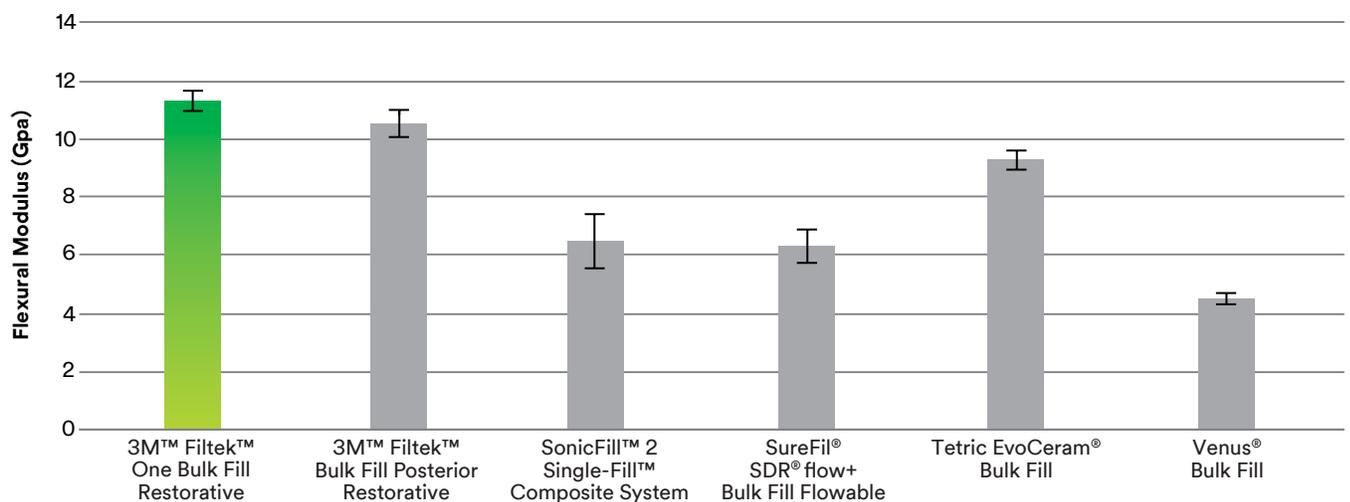


Figure 16: Flexural modulus of common bulk fill composites. Source: 3M internal data

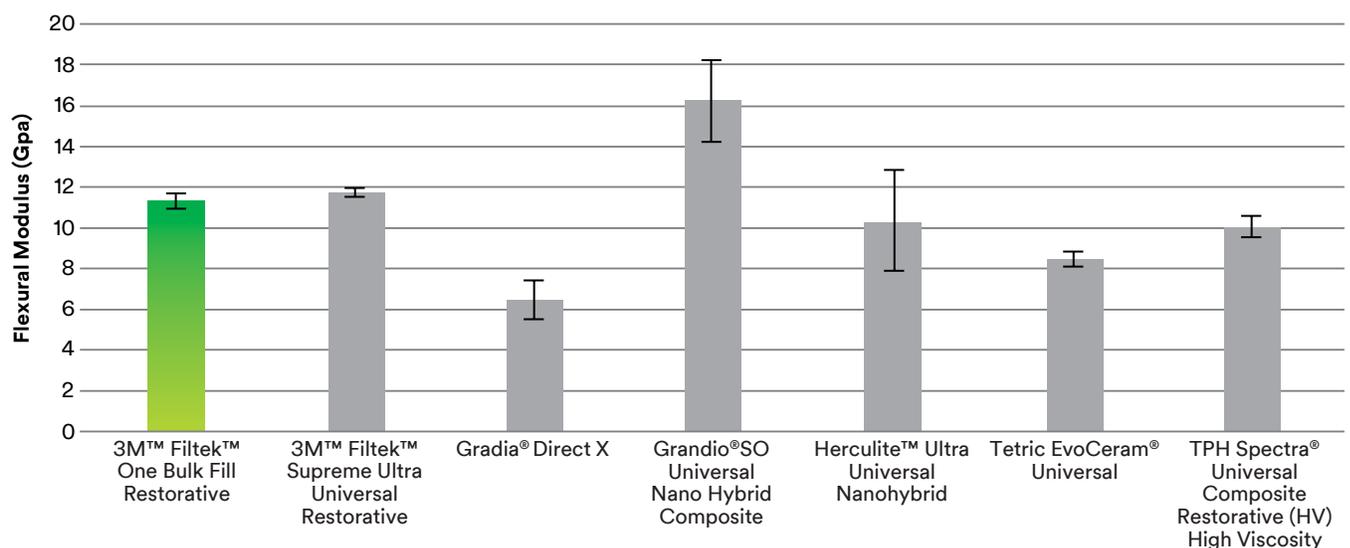


Figure 17: Flexural modulus of common incrementally placed universal composites. Source: 3M internal data

In-vitro 3-Body Wear

The wear rate was determined using an in-vitro 3-body wear test. In this test, composite (1st body) is loaded onto a wheel, which contacts another wheel, which acts as an “antagonistic cusp” (2nd body). The two wheels counter-rotate against one another, dragging abrasive slurry (3rd body) between them. Dimensional loss is determined by profilometry at the end of 200,000 cycles. In tests where wear is monitored at regular intervals, it is found to be linear. Consequently, wear rates can be predictive beyond the length of the actual test. The 3-body in-vitro wear of 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Posterior Restorative and significantly less than a number of bulk fill and incrementally placed composites (Figures 18, 19).

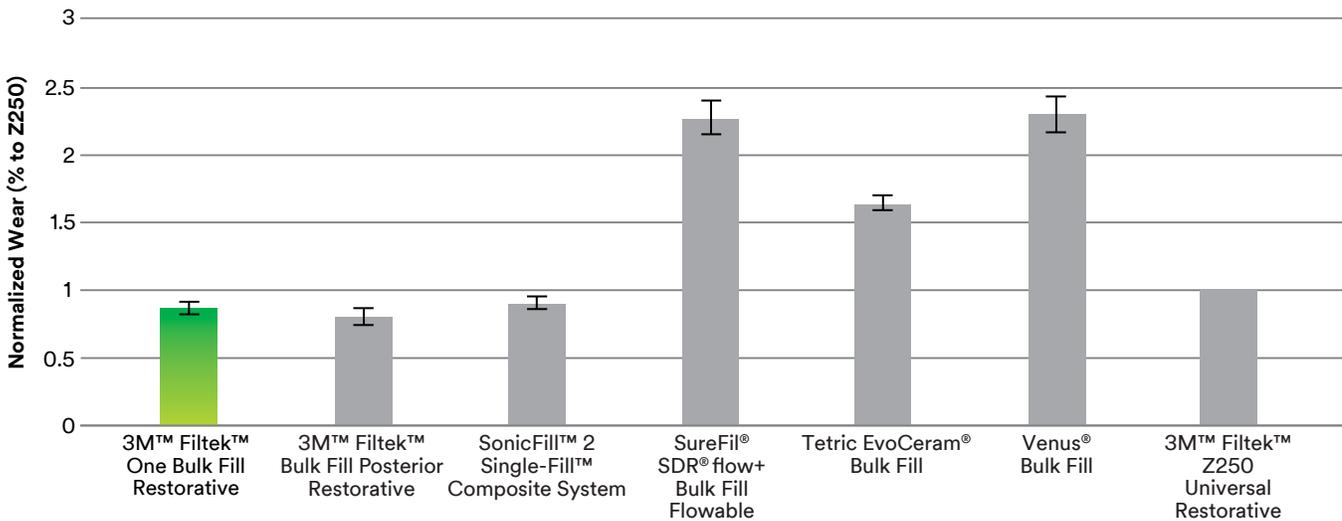


Figure 18: In-vitro 3-body wear of common bulk fill composites. Source: 3M internal data

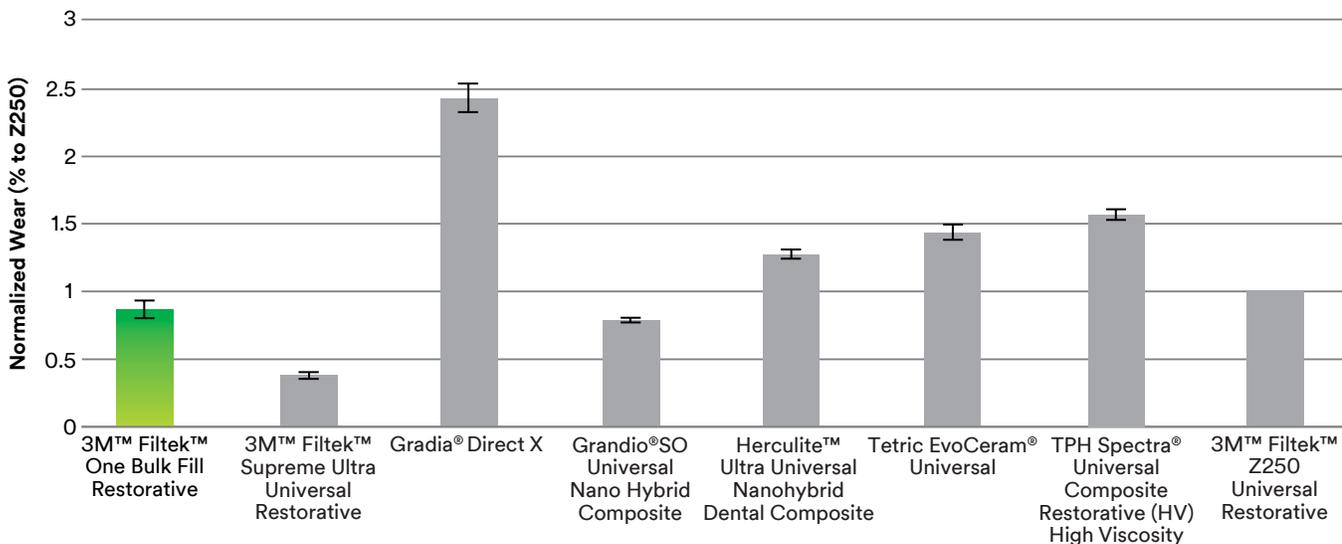


Figure 19: In-vitro 3-body wear of common incrementally placed universal composites. Source: 3M internal data

Fracture Toughness

The values reported for fracture toughness (K1c) are related to the energy required to propagate a crack. In this test, a short bar of material is cured. A notch is cut into it. The bar is placed on a fixture that supports either end and an anvil is positioned above the notch. The anvil presses down until the bar breaks. Higher values of K1c mean the material is more resistant to fracturing. The fracture toughness of 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative and higher than Tetric EvoCeram® Bulk Fill, SonicFill™ 2 Single-Fill™ Composite System, SureFil® SDR® flow+ Bulk Fill Flowable, Herculite™ Ultra Universal Nanohybrid Dental Composite and Gradia® Direct X (Figures 20, 21).

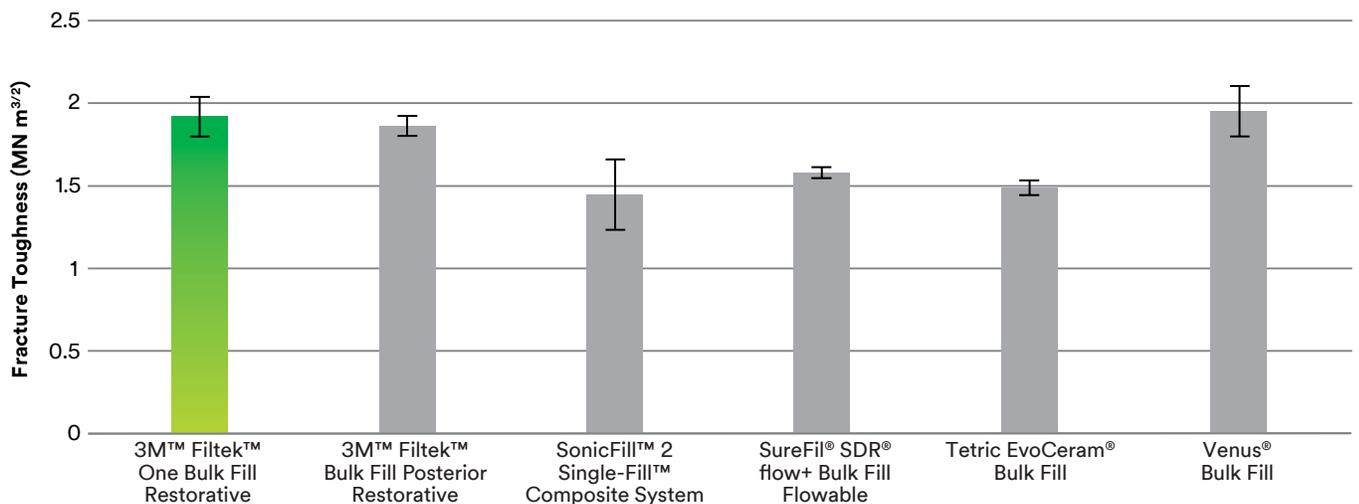


Figure 20: Fracture toughness of common bulk fill composites. Source: 3M internal data

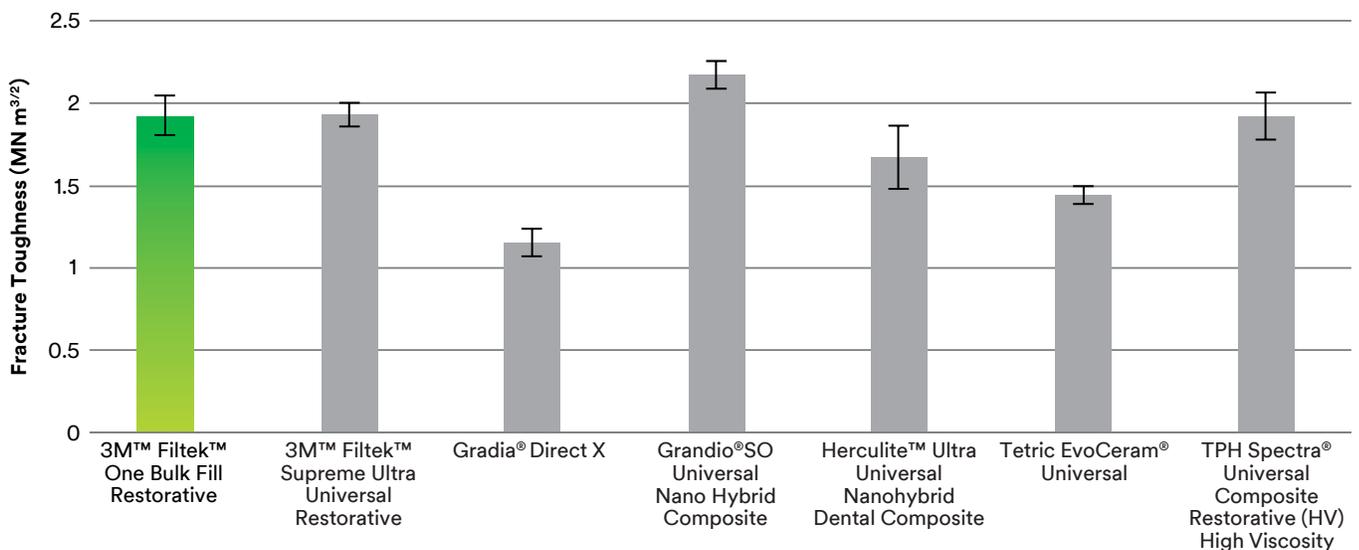


Figure 21: Fracture toughness of common incrementally placed universal composites. Source: 3M internal data

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. The flexural strength of 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative and higher than the competitive bulk fill and universal composites (Figures 22, 23).

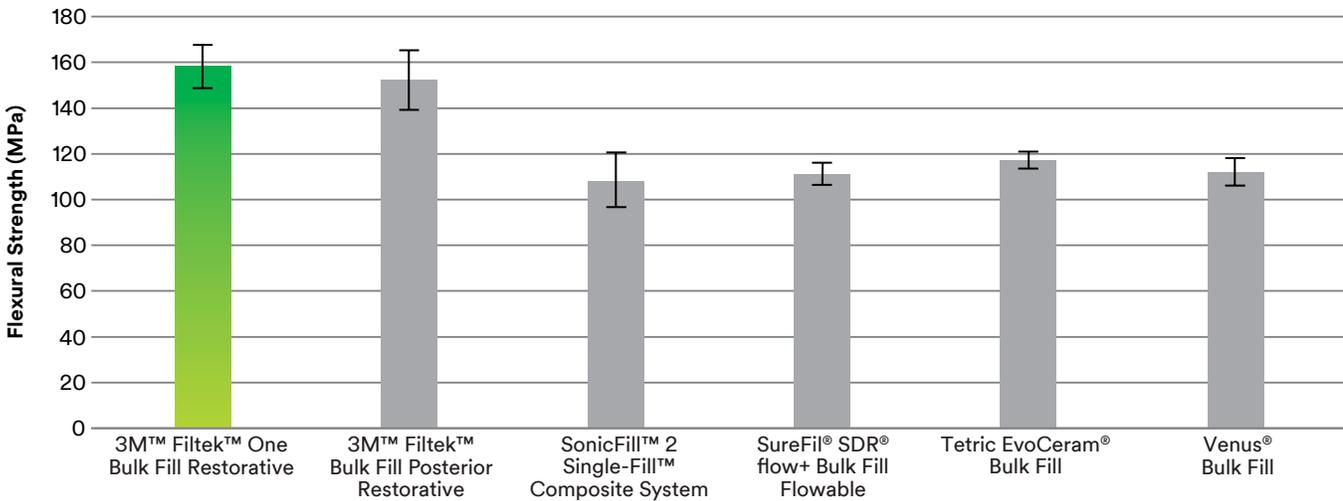


Figure 22: Flexural strength of common bulk fill composites. Source: 3M internal data

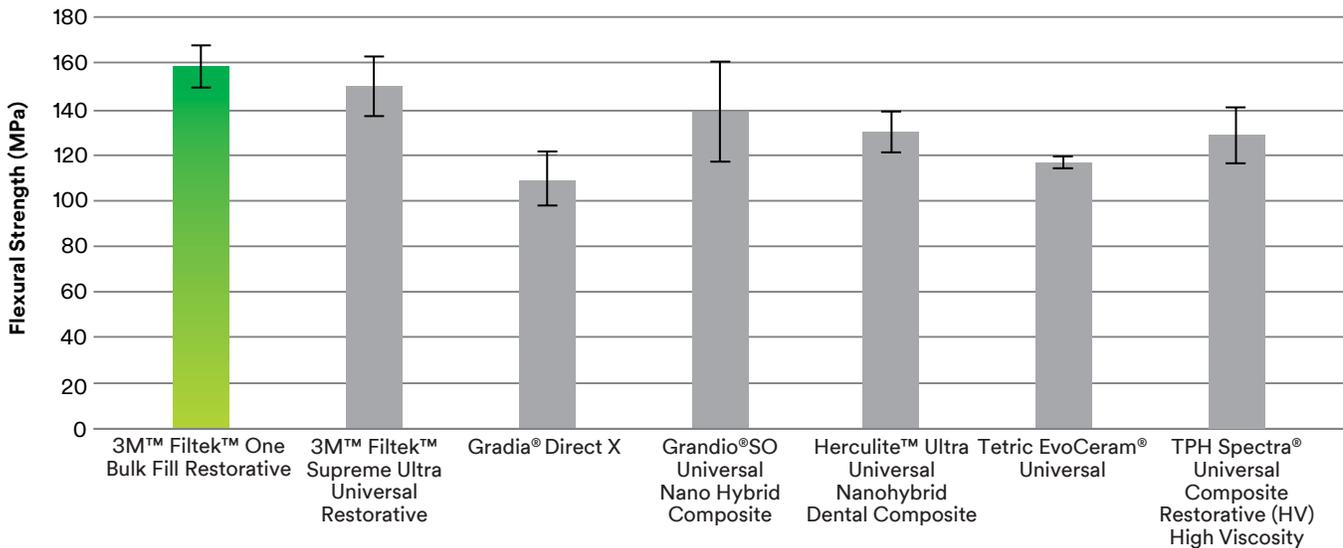


Figure 23: Flexural strength of common incrementally placed universal composites. Source: 3M internal data

Compressive Strength

Compressive strength is particularly important to resist the forces of chewing. Rods are made of the material and simultaneous forces are applied to the opposite ends of the sample length. The sample failure is a result of shear and tensile forces. The compressive strength of 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Restorative and 3M™ Filtek™ Supreme Ultra Universal Restorative, higher than SonicFill™ 2 Single-Fill™ Composite System, SureFil® SDR® flow+ Bulk Fill Flowable, Gradia® Direct X and equivalent to the other universal composites listed (Figures 24, 25).

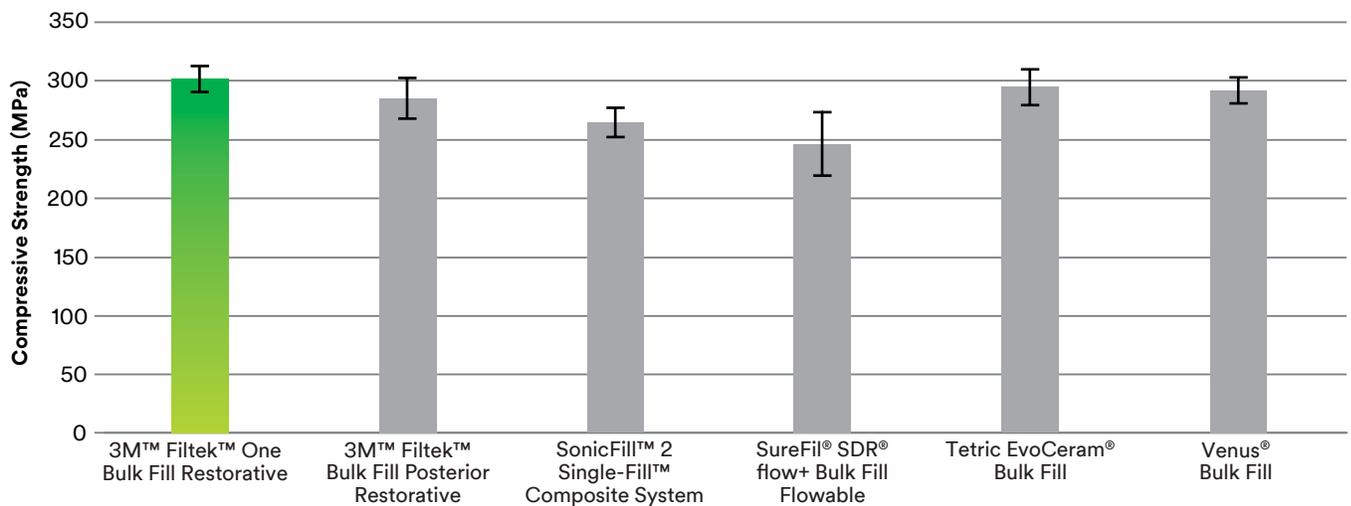


Figure 24: Compressive strength of common bulk fill composites. Source: 3M internal data

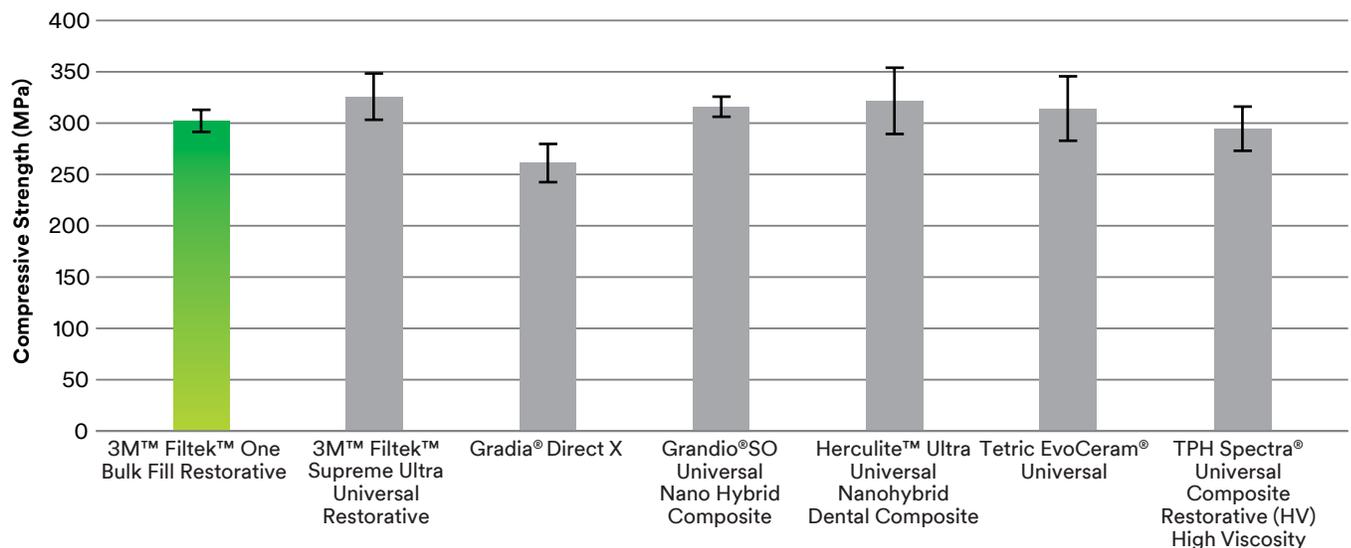


Figure 25: Compressive strength of common incrementally placed universal composites. Source: 3M internal data

Polish Retention

Toothbrush Abrasion

Composite materials were shaped into tiles and thoroughly cured. The surfaces were polished wet using a Buehler variable-speed grinder-polisher to remove the air-inhibited layer and to ensure a uniform surface. They were stored in water at 37°C for 24 hours. Gloss was measured. The samples were brushed with toothpaste and a toothbrush that was mounted on an Automatic Toothbrush Machine. Gloss measurements were taken after every 1500 cycles until the completion of 6000 toothbrush strokes. The polish retention of 3M™ Filtek™ One Bulk Fill Restorative is equivalent to 3M™ Filtek™ Bulk Fill Posterior Restorative and significantly higher than the competitive bulk fill and universal composites tested (Figure 26, 27).

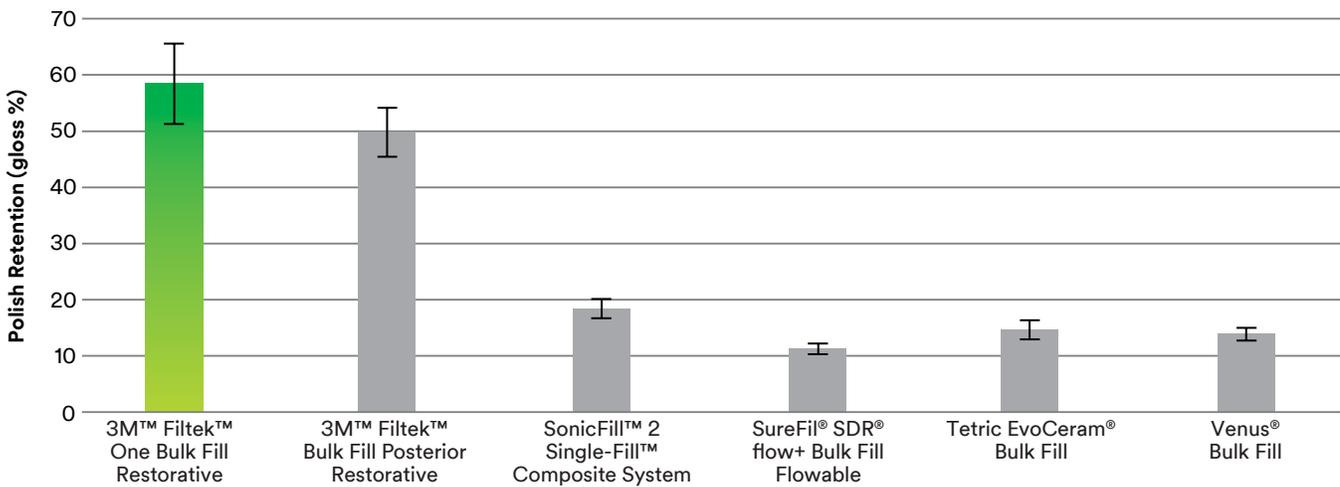


Figure 26: Polish retention of common bulk fill composites. Source: 3M internal data

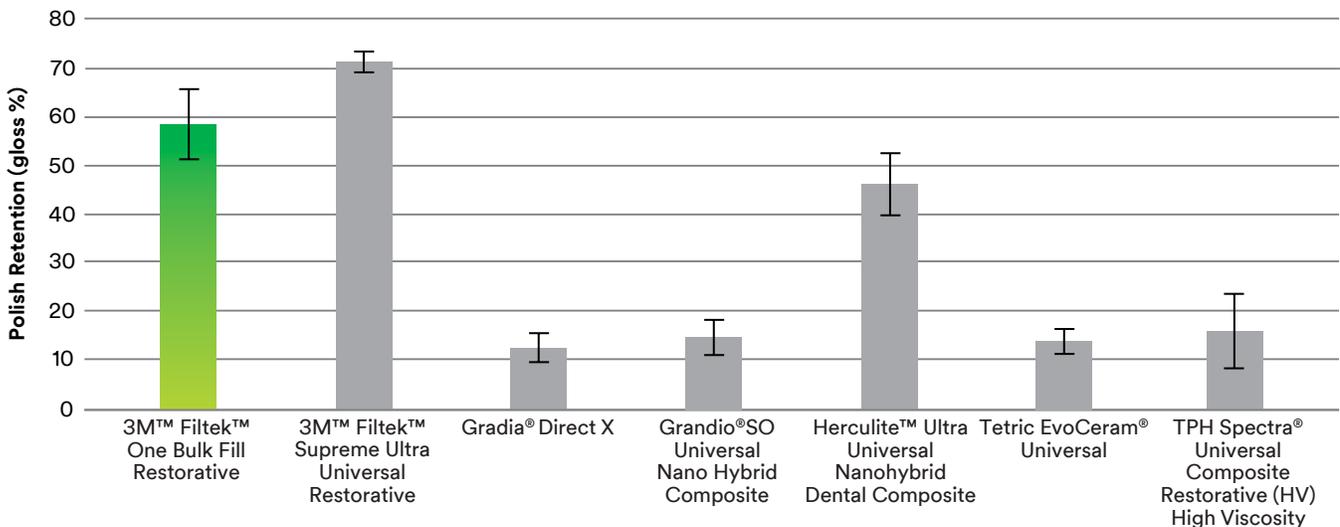


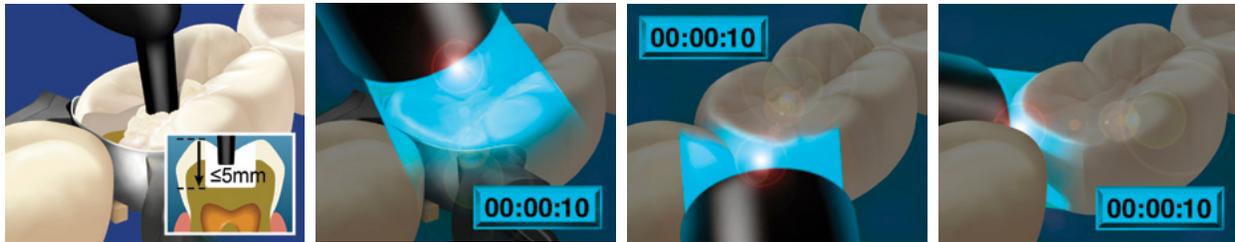
Figure 27: Polish retention of common incrementally placed universal composites. Source: 3M internal data

Curing Protocols

The curing protocol is dependent on the class of restoration and the intensity of the curing light. The illustrations and protocols below provide the details for proper curing. For specific details of each of these restorations, refer to the detailed Instructions for Use.

Class II Restorations

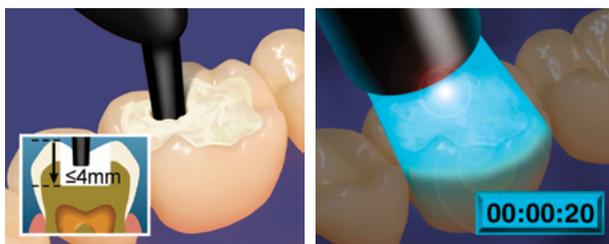
For Class II restorations that are up to 5 mm in depth, it is required to provide three separate curing cycles, an initial cure of the occlusal surface followed by removal of the matrix band and separate cures of the buccal and lingual surfaces.



For curing lamps that have an intensity of 1000mw/cm² or greater, the curing cycles are 10 seconds per surface. For curing lamps with less intensity (550–1000 mw/cm²), the curing cycles are 20 seconds per surface.

Class I Restorations

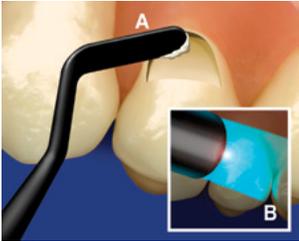
For Class I restorations that are a maximum of 4 mm in depth, a single cure from the occlusal surface is sufficient.



For curing lamps that have an intensity of 1000mw/cm² or greater, the curing cycle is 20 seconds on the occlusal surface. For curing lamps with less intensity (550–1000 mw/cm²), the curing cycle is 40 seconds on the occlusal surface.

Anterior Restorations

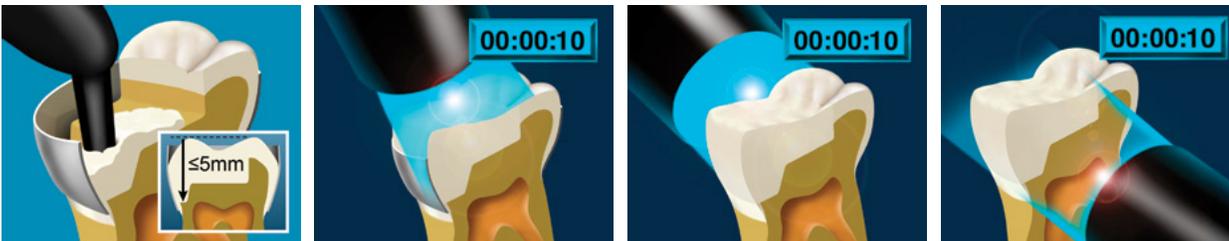
For anterior restorations that are 3 mm or less in depth, a single cure of the material is sufficient.



For curing lamps that have an intensity of $1000\text{mw}/\text{cm}^2$ or greater, the curing cycle is 10 seconds on the occlusal surface. For curing lamps with less intensity ($550\text{--}1000\text{ mw}/\text{cm}^2$), the curing cycle is 20 seconds on the occlusal surface. This curing protocol would also apply for shallow Class I restorations that are 3 mm or less in depth.

Core Build-up Restorations

A large core build-up restoration can be placed in depths up to 5 mm in a single increment and utilizes the same curing protocol as the Class II restoration. There are three separate curing cycles on the occlusal, buccal and lingual surfaces.



For curing lamps that have an intensity of $1000\text{mw}/\text{cm}^2$ or greater, the curing cycles are 10 seconds per surface. For curing lamps with less intensity ($550\text{--}1000\text{ mw}/\text{cm}^2$), the curing cycles are 20 seconds per surface.

Questions and Answers

What is the difference between 3M™ Filtek™ One Bulk Fill Restorative and 3M™ Filtek™ Bulk Fill Posterior Restorative?

Filtek One Bulk Fill Restorative was designed to provide more opacity and, therefore, a more esthetic version of Filtek Bulk Fill Posterior Restorative while still providing all of the excellent product performance features (delivery, handling, adaptation, depth of cure and physical properties). Dentists who have used Filtek One Bulk Fill Restorative clinically have rated the esthetics to be better than their current bulk fill materials, including Filtek Bulk Fill Posterior Restorative material.

What is contrast ratio and opacity?

Contrast ratio is the actual measurement of a material that tells us how opaque or translucent a material is. The higher the contrast ratio, the higher the opacity. The average contrast ratio for Filtek Bulk Fill Posterior Restorative's five shades is 43, while the average contrast ratio for Filtek One Bulk Fill Restorative's five shades is 51. Therefore, Filtek One Bulk Fill Restorative is more opaque.

Why is opacity important?

For large posterior restorations and restorations with underlying stains, if a material is too translucent, it may appear grayish or allow underlying stains to show through. Therefore, in these situations, a material with higher opacity is beneficial to provide better esthetics.

The higher opacity of Filtek One Bulk Fill Restorative is actually in the range of many traditional universal composites and could potentially meet the dentist's needs for both posterior and anterior restorations.

Does Filtek One Bulk Fill Restorative still provide all of the other properties of Filtek Bulk Fill Posterior Restorative?

Yes, Filtek One Bulk Fill Restorative was designed to ensure that it provided the same type of features, indications and properties as Filtek Bulk Fill Posterior Restorative. Therefore, it can be a direct replacement.

What allows Filtek One Bulk Fill Restorative to be placed in bulk in Class I and Class II cavities?

The unique AFM and AUDMA monomers provide stress relief during curing and allow the placement of a single increment. The Smart Contrast Ratio Management allows for the 4 and 5mm depth of cure of a single increment following the recommended curing protocols. The excellent handling of the pastes allows for excellent adaptation to the cavity walls when placed in a single increment.

What is the benefit of 3M™ Filtek™ One Bulk Fill Restorative vs. incrementally placed composites?

The primary benefit is the significantly simplified and faster one-step placement for Class I and Class II restorations. Additionally, an in-vitro simulated operatory study has shown that there are significantly less proximal margin defects in Class II restorations when using Filtek One Bulk Fill Restorative compared to incrementally placed universal composites.

What is the difference between polymerization shrinkage and polymerization stress?

Polymerization shrinkage, when expressed as a volume, is simply the decrease in volume of the composite as it shrinks due to the curing process.

Polymerization stress is a measurement of the impact on the interface of the composite, adhesive and tooth as a result of the composite shrinking upon curing. Polymerization stress is a function of the shrinkage and other properties of the resin and composite and not only of the actual shrinkage value alone. Polymerization stress is determined via a cusp deflection methodology and is more indicative of the actual clinical placement concerns.

Why is low polymerization stress important?

Polymerization shrinkage stress can contribute to adhesive failure between the tooth and composite, which may result in post-operative sensitivity, marginal leakage and marginal discoloration. If the bond does not fail, polymerization stress may cause fracture of the enamel adjacent to the cavosurface, which may contribute to marginal ditching over time. Polymerization stress may also cause an inward deflection of the cusps in Class II restorations.

How do the monomers in Filtek One Bulk Fill Restorative help relieve polymerization stress?

Filtek One Bulk Fill Restorative contains two novel methacrylate monomers that, in combination, act to lower polymerization stress. One monomer, a high-molecular-weight aromatic dimethacrylate (AUDMA) decreases the number of reactive groups in the resin. This helps to moderate the volumetric shrinkage as well as the stiffness of the developing and final polymer matrix—both of which contribute to the development of polymerization stress.

The second unique methacrylate represents a class of compounds called addition fragmentation monomers (AFM). During polymerization, AFM reacts into the developing polymer as with any methacrylate, forming cross-links between adjacent polymer chains. AFM contains a third reactive site that may cleave through a fragmentation process during polymerization. This process provides a mechanism for the relaxation of the developing network and subsequent stress relief. The fragments, however, still retain the capability to react with each other or with other reactive sites of the developing polymer. In this manner, stress relief is possible while maintaining the physical properties of the polymer.

Is this a nano-filled material?

The filler system uses the same nanofiller technology as 3M™ Filtek™ Supreme restoratives—a combination of silane-treated nanoclusters and individual silane-treated nanosilica and nanozirconia. In addition, it contains nano-scale ytterbium trifluoride to impart improved radiopacity.

How does the radiopacity compare to the other 3M composites?

3M™ Filtek™ One Bulk Fill Restorative and 3M™ Filtek™ Bulk Fill Posterior Restorative are more radiopaque than our other composite materials. We achieve this high level of radiopacity by incorporating nano ytterbium trifluoride.

Why is Filtek One Bulk Fill Restorative described as a BPA-free dental material?

The BisGMA monomer that is used in our other composites has been replaced with a dimethacrylate that does not use Bisphenol A in its synthesis. This was done to maximize the stress relief during polymerization.

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