3M

Filtek™ P60

Posterior Restorative System

Technical Product Profile

Table of Contents

Background

The market for filling materials continues to proceed through an evolutionary process that is fueled by a combination of factors including:

- the desire for new materials by dentists
- the inability of dental materials to provide consistent, esthetic restorations
- the efforts of dental manufacturers to optimize composite properties most desired by dentists
- the dentists' increased understanding of the materials' performance characteristics
- the changes in the industry environment including reimbursement changes and patient demands.

Composite materials have been used in dental practices to restore teeth since 3M first introduced a composite to the dental market in 1964. The early materials were chemically cured. These tooth-colored materials provided better esthetics than amalgam. However much had to be learned about the physical properties that were required to survive in the oral environment. High wear, color changes, and lack of bonding to tooth surfaces were some of the issues associated with these early materials.

Significant advances have been made since these early materials which have improved upon many of the early materials' weaknesses. Adhesive systems have been developed that adhere well not only to enamel (with acid etching), but to moist dentin even when placed in a humid environment. Composites have been made stronger, more wear resistant and more color stable. Both types of materials (composites and adhesives) were made curable on demand with high intensity lights that emit light in the wavelength range of 400-500 nm.

Prior to the late 1980's composites were developed that were specific to restoration type, i.e. materials were designed for anterior or posterior use. The main distinction between these materials was the high esthetic requirements for anterior use vs. the high strength requirement for posterior use. One material was not available that offered both. The gap between the two types of materials was very wide.

One of 3M's first entries in the posterior composite marketplace was P-10™ Resin Bonded Ceramic (RBC). This material reflected the state of the art in self-cured (auto-cured) composites. In 1984 3M introduced a light-cured posterior composite, P-30™ Light Cure Resin Bonded Ceramic (RBC). P-30 RBC restorative also utilized resin bonded ceramic technology to produce a material that was more esthetic than amalgam, strong, and wear resistant. Many P-10 RBC and P-30 RBC restorations are still functioning clinically. P-50™ Light Cure Resin Bonded Ceramic became available in 1987 replacing P-30 RBC restorative. It employed a high filler loading of a proprietary synthetic filler. P-50 RBC offered a strong, wear resistant, moderately esthetic composite to dentists. The clinical success of P-50 RBC has been documented with posterior clinical studies that supported its receipt of the ADA Seal of Acceptance.

In the late 1980's composite materials were developed to be used both for anterior and posterior restorations. These materials narrowed the gaps between esthetics and strength. Dentists were now able to use one composite material for all of their composite restorative use. The reduction in inventory (one set of shades) and ease of material selection were additional benefits realized by the dental practitioner.

3M entered this "universal composite" marketplace in 1992 with 3M™ Z100™ Restorative. Z100 restorative provided dentists with a material that provided very good esthetics, strength and wear resistance. Three clinical studies have documented the clinical success. Two of the studies, conducted at Creighton University and the University of Manitoba, examined the overall clinical performance over a 4-year period. Both of these studies concluded that Z100 restorative is a viable and clinically acceptable material for use in posterior restorations.

The third study, conducted at Catholic University at Leuven, closely examined the wear of the material using a computerized measuring technique accurate to within 1 micron. The 4-year clinical results of contact-free occlusal areas and occlusal contact areas demonstrated this material has wear similar to amalgam. Additionally, the wear rate of Z100 restorative on enamel in occlusal contact areas is comparable to the occlusal contact wear for enamel on enamel. In an ideal situation, the wear of material from a composite restorative should match that of enamel.

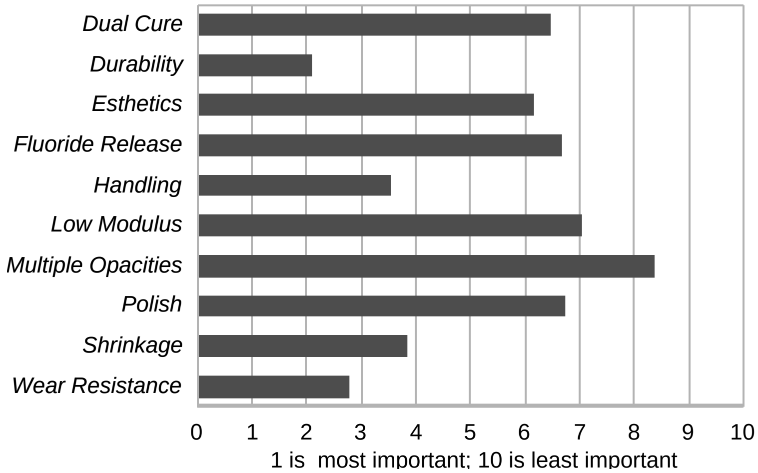
Other studies by independent research organizations (who use a wide variety of practitioners to conduct their studies) have confirmed the favorable results for posterior restorations of the controlled clinical studies. Anterior 5-year clinical results were also reported by one of these organizations. Again the results indicated the high level of patient and dentist satisfaction with the performance of Z100 restorative (*The Dental Advisor*, August, 1998, Vol. 15, No. 6).

The current market is beginning to demand separate materials for the anterior and the posterior. Some dentists are demanding better esthetics in anterior restorations than is currently provided by many universal materials. In the last two years, composites have been introduced that claim to help the dentist with some of the problem areas associated with placing posterior composites, e.g., formation of interproximal contacts and ease of placement. Hence, the development and introduction of 3M™ Filtek™ P60 Posterior Restorative.

The Development Process

Three years ago, a survey was sent to 3M™ Z100™ Restorative users. The participants were asked to rank 10 attributes for a material used for posterior restorations. The results were not surprising and confirmed previously known restorative requirements for posterior use.

Figure 1. Importance

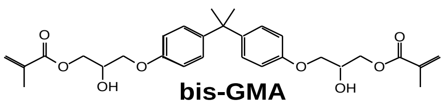


For posterior applications, durability and wear resistance were considered the most important, followed by handling and shrinkage. The other attributes could be grouped in one final category.

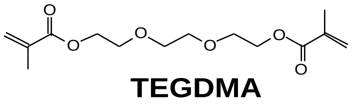
In subsequent research, dentists using Z100 restorative were asked what improvements could be made to Z100 to enhance the clinical performance. The top four responses were reduced shrinkage, better initial and sustained polish, improved marginal integrity and reduced post-operative sensitivity.

Chemistry

Examination of the Z100 composition established the belief that modifying the resin system could result in enhanced properties. The Z100 resin system consists of BIS-GMA (Bisphenol A diglycidyl ether dimethacrylate) and TEGDMA (tri[ethylene glycol] dimethacrylate).



The high concentration of a low molecular weight component, TEGDMA resulted in a system that offered the following advantages:

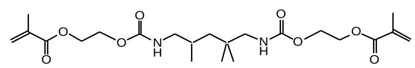


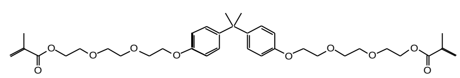
- The resultant high number of double bonds per unit of weight on a flexible backbone afforded the opportunity to have a high conversion of double bonds during polymerization.
- The low viscosity permits higher filler loading than with BIS-GMA alone.
- The high degree of crosslinking and compact molecule creates a very hard resin matrix.

However, the high TEGDMA concentration also allows for some opportunities for improvements.

- The relatively low molecular weight of TEGDMA contributes to the aging of an uncured composite.
- The low molecular weight and resultant high number of double bonds per unit of weight creates a high degree of crosslinking creating a very rigid, stiff composite with a relatively high level of shrinkage.
- TEGDMA is somewhat hydrophilic. Fluctuations in the moisture content of the paste can contribute to thickening and softening of the uncured paste. These fluctuations depend on the moisture content of the surrounding air under extreme conditions.

The new resin system of 3M™ Filtek™ P60 Posterior Restorative consists of 3 major components. In Filtek P60 restorative, the majority of TEGDMA has been replaced with a blend of UDMA (urethane dimethacrylate) and Bis-EMA(6)[1] (Bisphenol A polyetheylene glycol diether dimethacrylate). Both of these resins are higher molecular weight and therefore have fewer double bonds per unit of weight. The high molecular weight materials also impact the measurable viscosity. The higher molecular weight of the resin results in less shrinkage, reduced aging and a slightly softer resin matrix. Additionally these resins impart a greater hydrophobicity and are less sensitive to changes in atmospheric moisture.

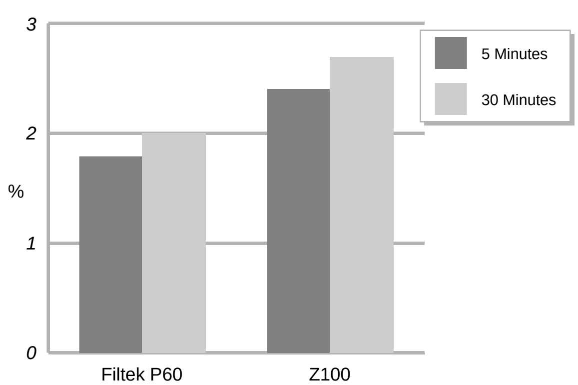

UDMA


bis-EMA(6)

The final resin composition was determined on the basis of physical properties, including compressive and diametral tensile strengths, shrinkage, wear resistance and customer handling preferences. A Simulated Operatory (handling evaluation in heated typodonts) was conducted to determine which resin system produced the most acceptable handling. By combining the data from all tests, a resin composition which optimized the property combination was chosen.

The reduction in shrinkage due to the new resin system was demonstrated using a mercury dilatometer. The actual volumetric shrinkage is measured via this method. In this test, a disc of uncured composite is placed on a glass stopper. This assembly is inserted into a mercury-filled chamber and polymerized through a window with a curing light. The curing light intensity is also measured through the window to determine the intensity of light reaching the sample. The volume change is recorded electronically over time. The final volume is measured and then the per cent volumetric shrinkage is calculated.

Figure 2. Volumetric Shrinkage



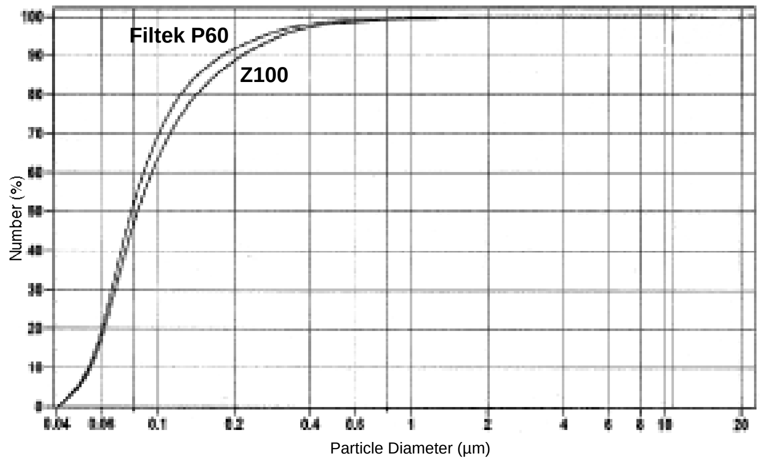
In this example, the samples were exposed for 40 seconds to a light with an intensity of approximately 400mW/cm^2. Filtek P60 restorative exhibited approximately 25% reduction of total volumetric shrinkage when compared to Z100 restorative at both 5 and 30 minutes.

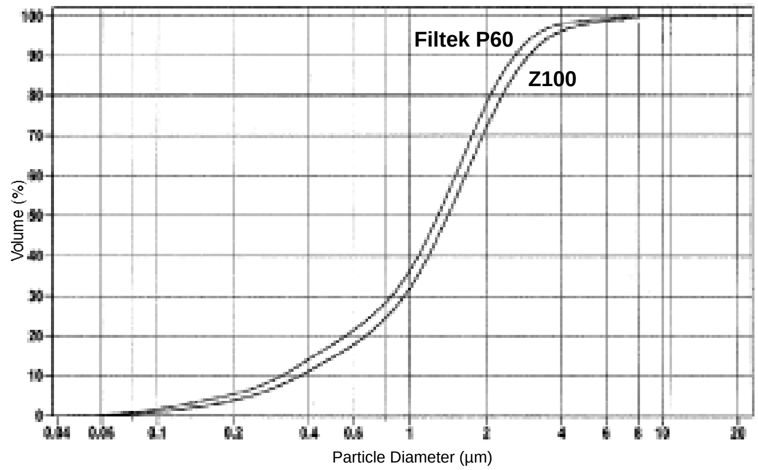
[1] Bis-EMA(6) contains, on average, 6 ethylene oxide groups per Bisphenol A grouping.

Filler

The filler in 3M™ Filtek™ P60 Posterior Restorative remains essentially the same as the 3M™ Z100™ Restorative filler. There have, however, been significant processing changes to maximize filler consistency. The particle size distribution is 0.01µm to 3.5µm with an average particle size of 0.6µm.

Figure 3. Cumulative Particle Size Distribution

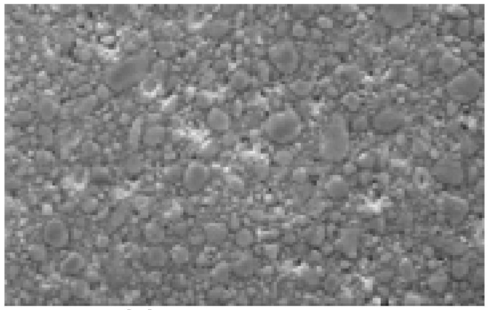




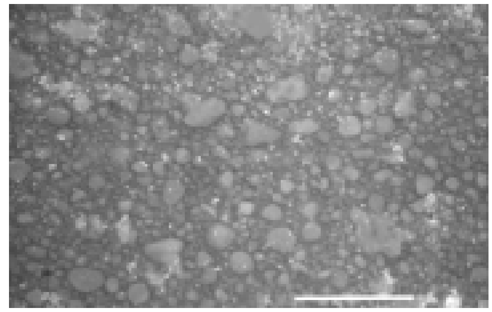
Using a Coulter® LS Particle Size Analyzer the filler distributions of Z100 restorative and Filtek P60 restorative were measured. The data was reported based on the number of particles or the volume the particles occupy at each particle diameter. Both provide a different insight into the distribution. The number of particles per diameter indicates the frequency a large particle may be encountered. One large particle can have the same volume of numerous small particles. Both charts report cumulative data, that is, the number or volume of particles at or below a specific diameter.

The data shows that the particle size distribution for Filtek P60 restorative contains a larger number of finer particles than found in Z100 restorative. The photos below were generated using scanning electron microscopy. Cured composite samples were photographed at 2500× magnification. However, even at this magnification the very small filler particles cannot be seen. Observation of the photos confirms the similarities between the size and shapes of Filtek P60 and Z100 restoratives.

Figure 4.
Cross Section SEMs



Filtek P60 Posterior Restorative



Z100 Restorative

Final Specifications

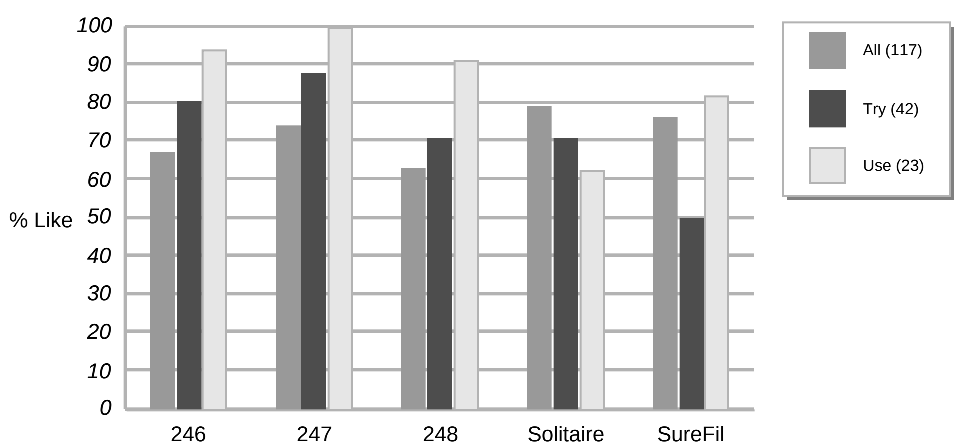
A global Simulated Operatory was conducted to determine final handling specifications for 3M™ Filtek™ P60 Posterior Restorative. One hundred seventeen dentists participated in a blind study that included three experimental pastes along with SureFil™ (Caulk/ Dentsply) and Solitaire™ (Heraeus Kulzer). The dentists participating in this study were screened on the basis of their universal product usage. During the Simulated Operatory dentists were asked about their awareness and usage of the new posterior products i.e., SureFil, ALERT™ (Jeneric/Pentron), Solitaire, Definite (Degussa) or Ariston pHc™ (Ivoclar Vivadent). Forty-two out of the 117 dentists in this research had tried these new products and 23 out of the 117 are continuing to use these products.

The participants evaluated three of the five pastes placing them in a posterior restoration in a heated mannequin (the dentists were unaware as to which materials they were actually handling). Handling acceptance was determined by simply asking the participants if they “liked” or disliked” the handling after placing the material.

In the charts below, the group of bars marked **All** indicates the results of all of the participants. The group of bars labeled **Tried** is the results from dentists who have actually tried the new posterior materials. The bar grouping labeled **Use** are only the dentists who are continuing to use the new posterior materials.

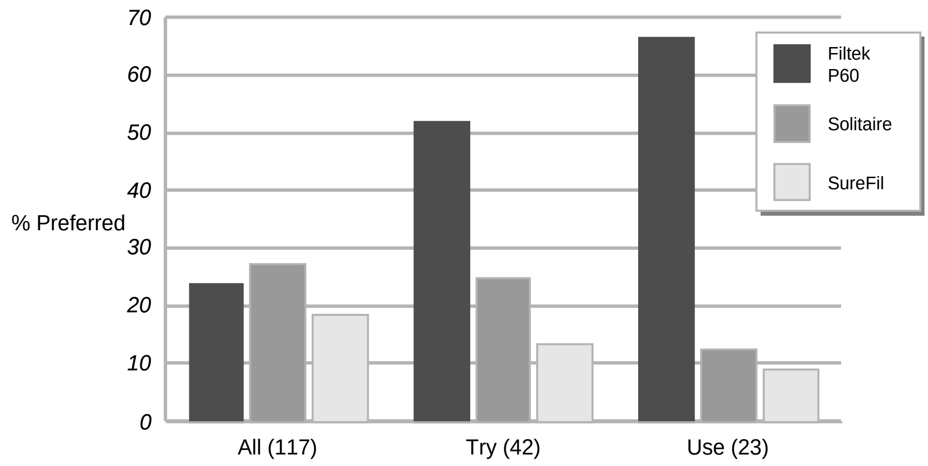
In the chart below, the experimental product formulations are indicated with the numbers 246, 247 and 248. The viscosity of the experimental material increases with increasing lot number. All lots of the experimental material displayed a very high acceptance. The comparative handling acceptability generally increases as the population is segmented from universal composite users (**All**) to dentists that have tried the new posterior products (**Try**) to those dentists that are continuing to use the new posterior products (**Use**).

Figure 5.
Handling Acceptance



After handling all three materials, dentists were asked which paste was preferred as a posterior restorative material (selecting one out of the three pastes handled). Although there were three experimental products involved in the study, the data presented below reflects only the experimental materials that are representative of 3M™ Filtek™ P60 Posterior Restorative. Examination of the groups of data (**All, Try, Use**) clearly demonstrates the presence of the segment of the population that has a predilection for this type of composite handling. Additionally, the data shows Filtek P60 restorative is strongly preferred over SureFil™ or Solitaire™ in this segment.

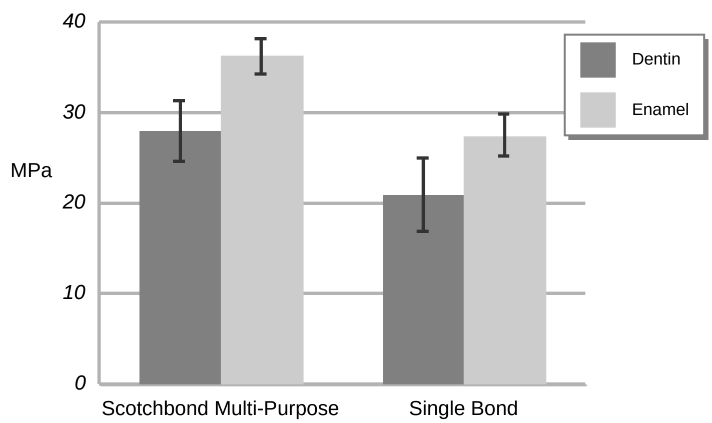
Figure 6.
Handling Preference



Product Description

Filtek P60 posterior restorative is an esthetic light cured, radiopaque composite specifically designed for use in posterior direct or indirect restorations. Bonding to the tooth structure is accomplished by using a dental adhesive system, such as 3M™ Single Bond or 3M™ Scotchbond™ Multi-Purpose Adhesive Systems.

Figure 7.
Adhesion



Filtek P60 restorative is packaged in bulk (multi-dose) syringes. Filtek P60 restorative is available in three of the most frequently requested shades for posterior use that correspond to the most commonly used shading system: A3, B2, C2.

The material is incrementally placed and cured in the cavity. The maximum increment thickness is 2.5mm. Each layer should be cured for 20 seconds.

Indications for Use

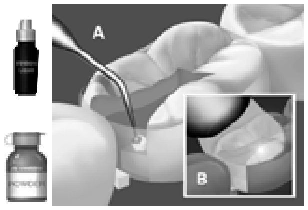
3M™ Filtek™ P60 Posterior Restorative is indicated for use in the following types of restorations.

- Direct posterior restorations
- Sandwich technique with glass ionomer resin material
- Cusp buildup
- Core buildup
- Splinting
- Indirect posterior restorations including inlays and onlays

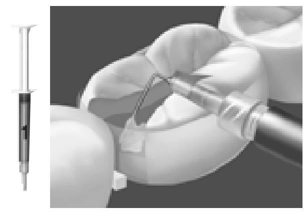
Technique Guides

Direct Posterior Restorations

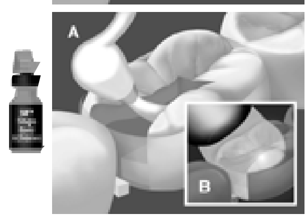
3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base
3M™ Single Bond Dental Adhesive System
3M™ Filtek™ P60 Posterior Restorative



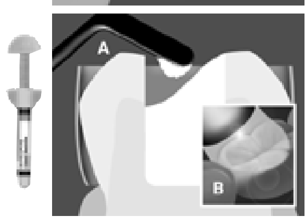
Prepare Tooth and Isolate.
Apply liner/base if desired:
- Mix a level scoop of Vitrebond powder and a drop of Vitrebond liquid on a mixing pad.
- Apply a thin layer of the liner/base to dentin surfaces using a ball applicator.
- Light cure for 30 seconds.



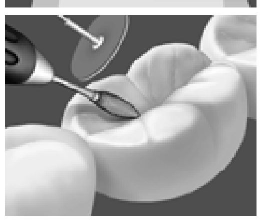
Etch:
- Apply 3M™ Scotchbond™ etchant to enamel and dentin. Wait 15 seconds. Etchant on Vitrebond base is not deleterious.
- Rinse.
- Blot excess water, leaving tooth moist.



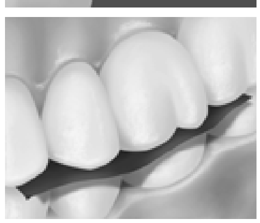
Bond:
- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of 3M Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



Place Restorative:
- Place 3M Filtek P60 restorative in increments less than 2.5mm.
- Light cure each increment for 20 seconds.



Finish and Polish:
- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ (extra-thin discs and Sof-Lex strips.



Check Occlusion:
- Check lateral and centric occlusion.
- Adjust if necessary.

Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

3M Glass Ionomer/Composite Laminate/Sandwich

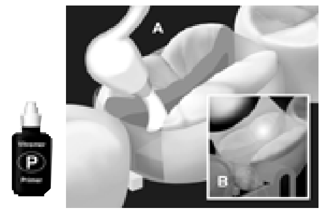
3M™ Vitremer™ Core Buildup/Restorative
3M™ Single Bond Dental Adhesive System
3M™ Filtek™ P60 Posterior Restorative

Indications

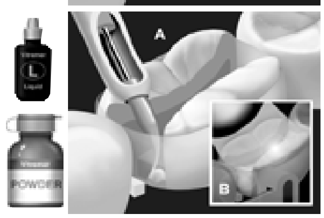
Direct posterior restorations where the benefits of glass ionomers and composite are desired.

Prepare/Prime:

Note that this technique is indicated where cavity design allows for a minimum composite restorative thickness of 2mm on the occlusal surface.

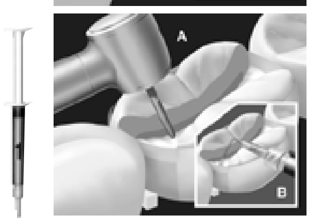


- Conservatively prepare the tooth; place matrix bands and wedges.
- Apply Vitremer primer for 30 seconds to all dentin surfaces; air dry.
- Light cure for 20 seconds.



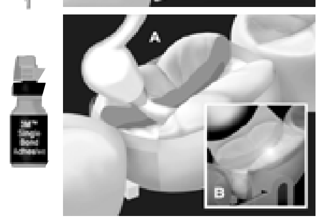
Apply Glass Ionomer:

- Mix Vitremer powder and liquid according to product instructions; back load into delivery tip.
- Syringe Vitremer restorative into the preparation, extending no further than apical to the proximal contact point.
- Light cure for 40 seconds.



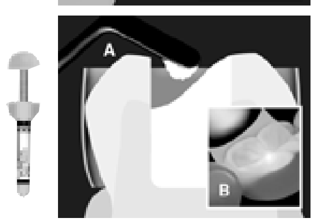
Freshen Preparation Margins/Etch:

- Using a rotary instrument, remove excess Vitremer restorative material from enamel margins and cavity walls that will be bonded.
- Apply 3M™ Scotchbond™ etchant to enamel and exposed dentin; wait 15 seconds, then rinse. Blot excess water, leaving tooth moist.



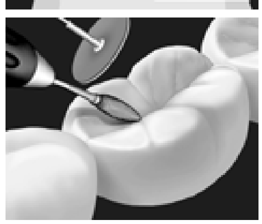
Bond:

- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel, dentin and Vitremer restorative base increment.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



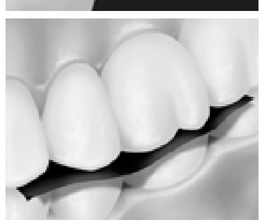
Place Restorative:

- Place 3M Filtek P60 restorative in increments less than 2.5mm.
- Light cure each increment for 20 seconds.



Finish and Polish:

- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ extra-thin discs and Sof-Lex strips.



Check Occlusion:

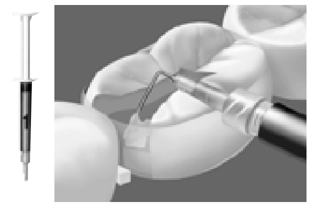
- Check lateral and centric occlusion.
- Adjust if necessary.

Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

3M™ Single Bond Dental Adhesive System
3M™ F2000 Compomer Restorative
3M™ Filtek™ P60 Posterior Restorative

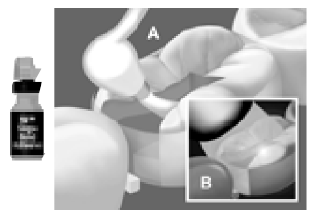
Indications

Direct posterior restorations where the benefits of a compomer and a composite are desired.



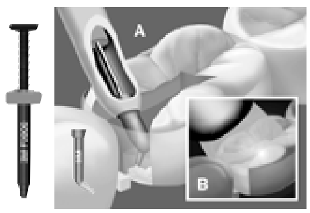
Etch:

- Apply 3M™ Scotchbond™ etchant to enamel and dentin; wait 15 seconds.
- Rinse.
- Blot excess water, leaving tooth moist.



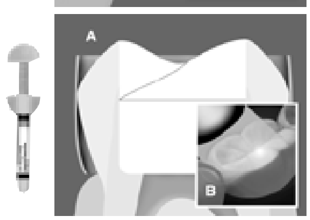
Bond:

- Using a fully saturated brush tip for each coat, apply 2 consecutive coats of Single Bond adhesive to enamel and dentin.
- Dry gently for 2-5 seconds.
- Light cure for 10 seconds.



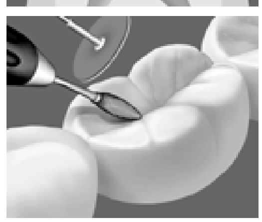
Place Compomer:

- Place F2000 compomer in increments.
- Place F2000 compomer no further than just apical to the proximal contact point.
- Remove any excess compomer inadvertently placed on enamel margins before light curing.
- Light cure each compomer increment for 40 seconds.



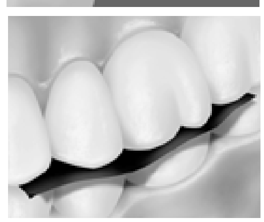
Place Composite:

- Place 3M Filtek P60 restorative in increments less than 2.5mm.
- Light cure each increment for 20 seconds.



Finish and Polish:

- Finish occlusal surface using an appropriate finishing instrument.
- Finish interproximal surfaces with 3M™ Sof-Lex™ Pop-on™ extra-thin discs and Sof-Lex strips.



Check Occlusion:

- Check lateral and centric occlusion.
- Adjust if necessary.

Please refer to instructions for more detailed information as well as precautionary and warranty information.
3M Customer Hotline 1-800-634-2249

Customer Evaluations

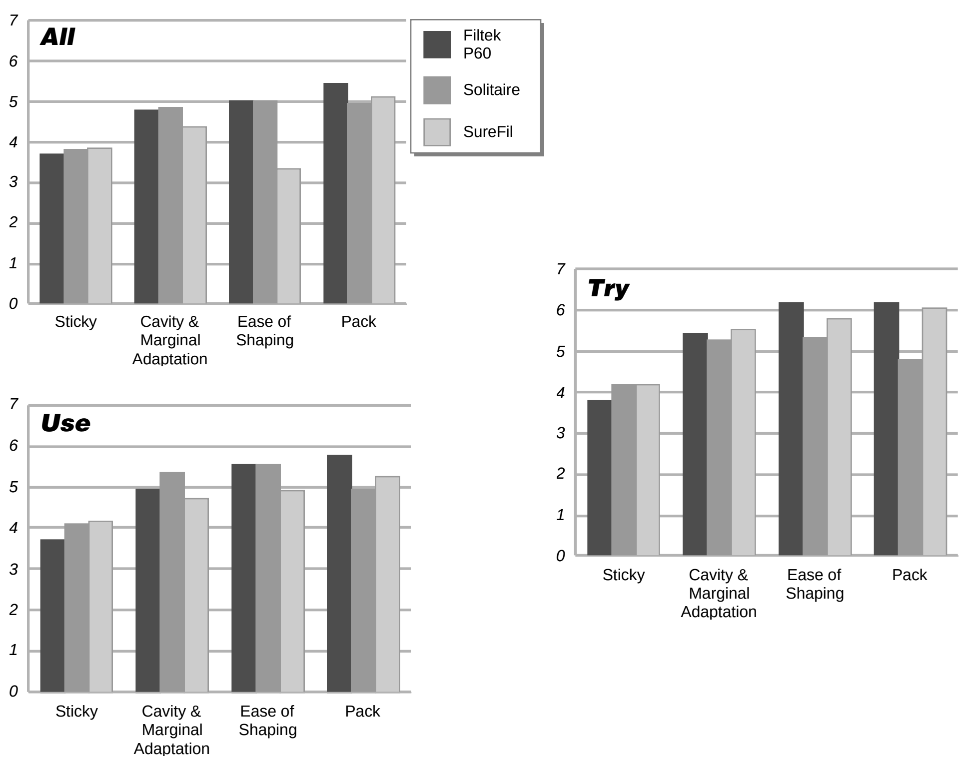
Global Simulated Operatory

In the Global Sim Op previously described, the ratings for specific handling attributes for posterior restorations were also determined. All attributes were rated on a seven-point scale as seen below.

Stickiness to instrument								
Not Sticky Enough	1	2	3	4	5	6	7	*Too sticky*
Cavity/marginal adaptation								
Does not adapt	1	2	3	4	5	6	7	*Adapts easily*
Ease of contouring or shaping								
Difficult	1	2	3	4	5	6	7	*Easy*
Packable								
Does not pack	1	2	3	4	5	6	7	*Very packable*

The ideal stickiness would be a rating of 4. For the other attributes the rating of an ideal material would be 7. The graphs below show the average ratings for the three groupings of dentists (see Final Specification discussion). The average ratings for stickiness, cavity and marginal adaptation for all materials were similar. While the differences between the average for ease of shaping and packability may not be statistically significant, the overall trend (focusing on the segment of the participants desiring this type of handling) indicates that 3M™ Filtek™ P60 Posterior Restorative was rated slightly higher than SureFil™ and Solitaire™.

Figure 8.
Posterior Handling



This page intentionally left blank.

Physical Properties

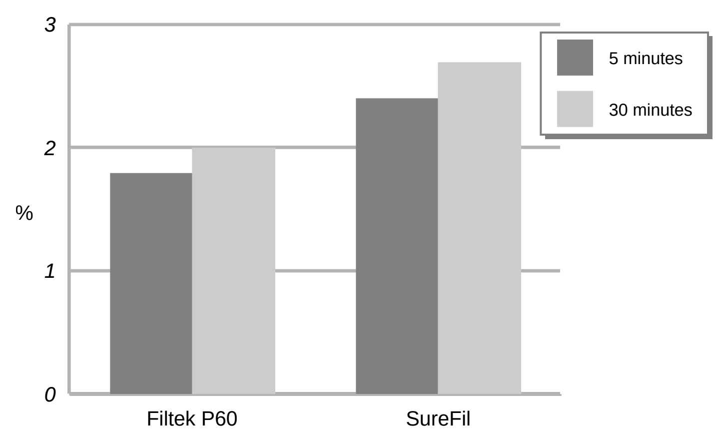
Materials

Designation	Product	Manufacturer
Solitaire	Solitaire™	Heraeus Kulzer
SureFil	SureFil™	Caulk/Dentsply
ALERT	ALERT™	Jeneric/Pentron
Z100	Z100™ Restorative	3M
P60	Filtek™ P60 Posterior Restorative	3M

Shrinkage

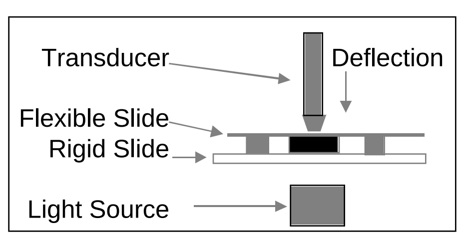
Shrinkage of composite is measured in a variety of methods. Some methods measure the total amount of shrinkage volumetrically or linearly. The dilatometer method was discussed earlier. Another method measures a portion of the shrinkage that occurs after the composite has lost the ability to flow (post-gel).

Figure 9. Volumetric Shrinkage (Dilatometer)



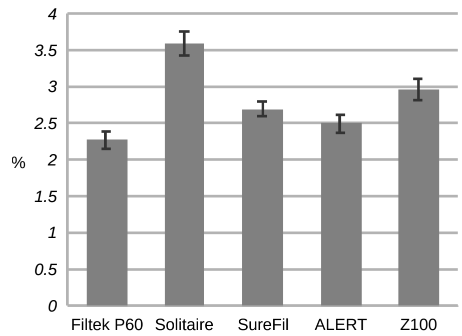
Volumetric Shrinkage

Another method for determining polymerization shrinkage was described by Watts and Cash (Meas. Sci. Technol. 2(1991) 788-794). In this method, a disc shaped test specimen 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.



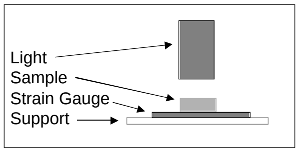
In this test, samples were exposed for 60 seconds to a 3M™ Visilux™ 2 Visible Light Curing unit. The final shrinkage was recorded 4 minutes after the end of light exposure. As the chart below shows, the value for 3M™ Filtek™ P60 Posterior Restorative is statistically lower than Solitaire™ and SureFil™. ALERT™ restorative exhibited statistically similar results as Filtek P60.

Figure 10. Volumetric Shrinkage



Post-Gel Shrinkage Strain

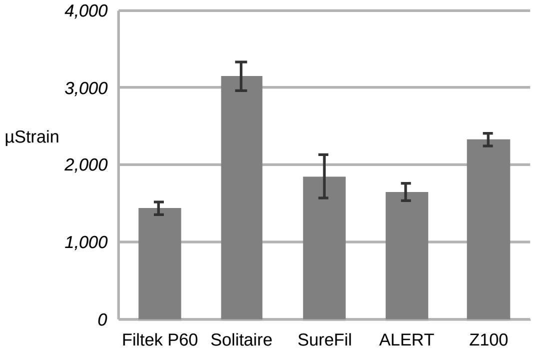
Post-gel shrinkage is reported to be the shrinkage that occurs after the material has gelled, i.e., the material has lost its ability to flow. Shrinkage stresses that occur in the pre-gel phase can be relieved readily by the flow of the material. However, stresses occurring during the post-gel phase cannot be relieved by material flow. These stresses remain built-up in the material and may cause fatigue within the material or at the composite-bond interface. Strain gauges have been shown to be an effective method for indicating linear post-gel polymerization shrinkage stress in composites.



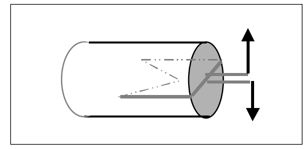
In this method a sample of composite was placed on top of a strain gauge. The composite samples were then light-cured for 60 seconds. The final shrinkage strain (in µStrain), which is the result of dimensional changes in the composite during polymerization, was recorded 4 minutes after the light was turned off.

The chart below depicts these final values. Filtek P60 restorative displayed significantly less shrinkage strain than Solitaire or 3M™ Z100™ Restorative.

Figure 11. Post-Gel Shrinkage Strain



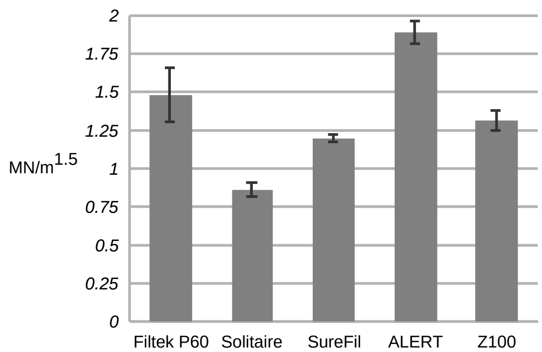
Fracture Toughness



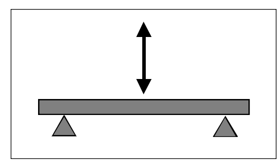
The values reported for fracture toughness (K_{IC}) are related to the energy required to propagate a crack. In this test a short rod of material is cured. A chevron or notch is cut into the cylinder and the parts on either side of the chevron are pulled apart.

Below are the 24-hour values for wet fracture toughness. The wet fracture toughness for 3M™ Filtek™ P60 Posterior Restorative was determined to be significantly higher than SureFil™ and Solitaire™. The value for Filtek P60 restorative was statistically similar to 3M™ Z100™ Restorative and statistically lower than ALERT™.

Figure 12.
Fracture Toughness



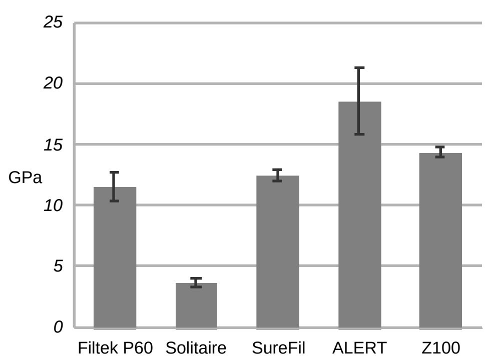
Flexural Modulus



Flexural modulus is a method of defining a material's stiffness. A low modulus indicates a flexible material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end.

The flexural modulus value for Filtek P60 restorative was intermediate. It was statistically lower than the flexural modulus for ALERT and Z100 restorative but was statistically higher than the flexural modulus for Solitaire.

Figure 13.
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. As shown in the graph below the flexural strength of 3M™ Filtek™ P60 Posterior Restorative was statistically higher than the value for ALERT™. The flexural strength values of the other materials tested were not significantly different from Filtek P60 restorative.

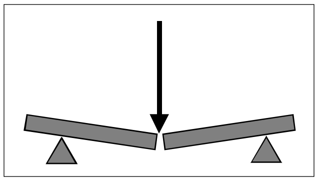
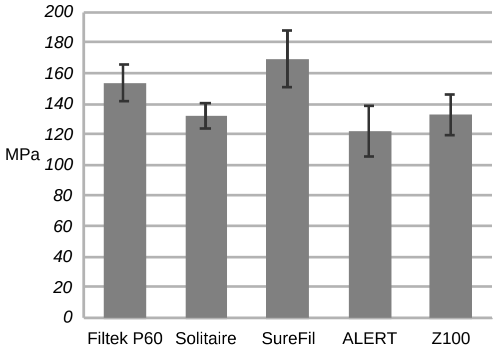
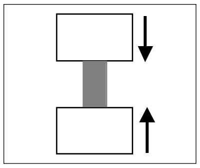


Figure 14.
Flexural Strength



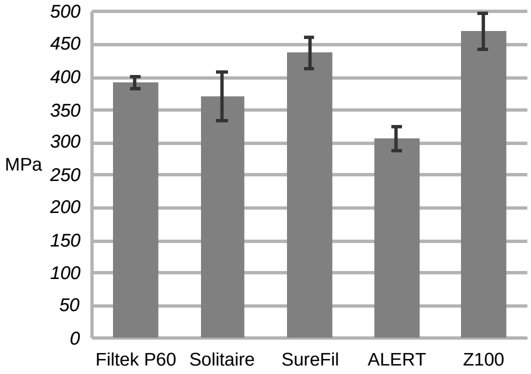
Compressive and Diametral Tensile Strength

Compressive strength is particularly important because of chewing forces. 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.

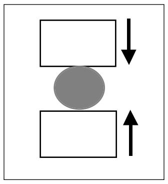


The compressive strengths of various materials are shown below. The value obtained for Filtek P60 restorative was not statistically different from SureFil™ or Solitaire™. However it was significantly higher than ALERT.

Figure 15.
Compressive Strength

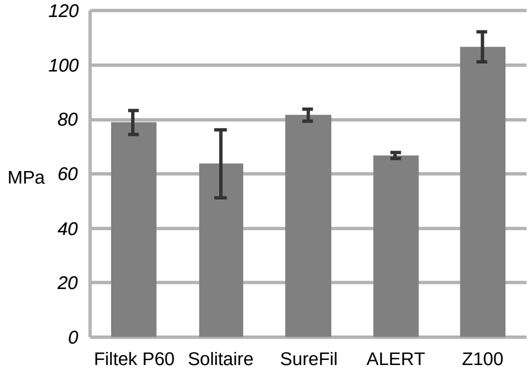


Diametral Tensile strength is measured using a similar set up. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs.



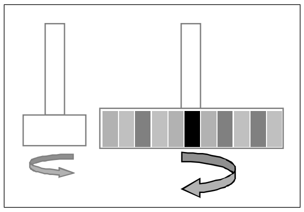
The diametral tensile strength of 3M™ Filtek™ P60 Posterior Restorative was significantly higher than Solitaire™. The value for Filtek P60 restorative was not statistically different from ALERT™ or SureFil™. These data are reported in the chart below.

Figure 16. Diametral Tensile Strength



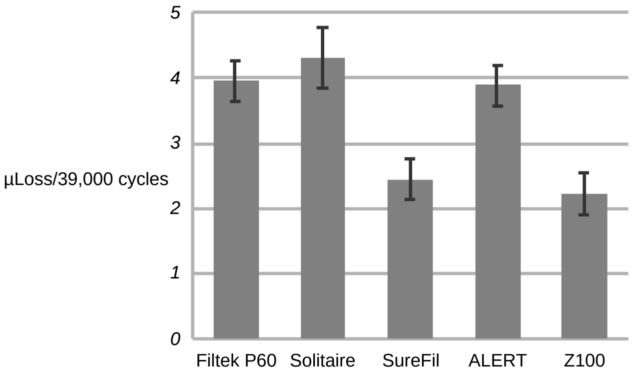
Wear

The wear rate was determined by an in-vitro 3-body wear test. In this test, composite (1st body) is loaded onto a wheel (shaded slots in the diagram) which contacts another wheel which acts as an "antagonistic cusp" (2nd body). The two wheels counter-rotate against one another dragging an abrasive slurry (3rd body) between them. Dimensional loss during 156,000 cycles is determined by profilometry at regular intervals (i.e., after every 39,000 cycles). As the wear in this method typically follows a linear pattern, the data is plotted using linear regression. The wear rates, i.e., the slope of the lines, are determined. The comparison of rates reduces some of the variability in the test due to sample preparation and can be predictive of anticipated wear beyond the length of the actual test.



The wear rate data shown below indicates the wear rate of Filtek P60 restorative is intermediate amongst the other materials tested.

Figure 17. Wear



Particle Size Distribution

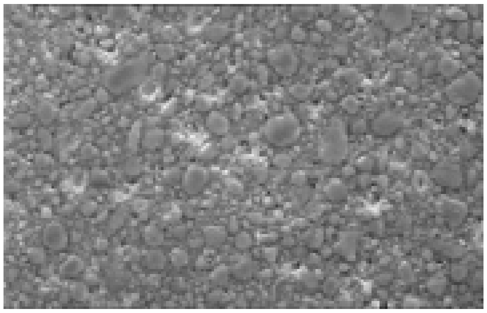
Cross Section SEM

In this column are SEMs (scanning electron micrographs) of cured universal composites in cross section. Observations of the particle size distributions and shapes can be made by comparing these photos. All samples are magnified at 2500×. However, even at this magnification, the very small filler particles are not visible.

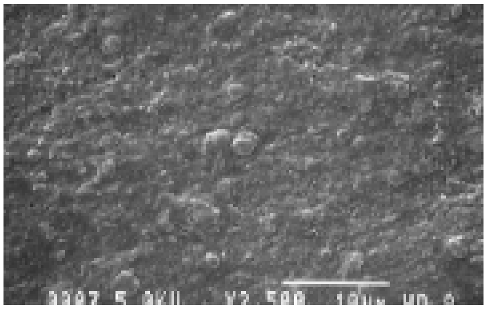
Surface SEM After Wear Wheel Abrasion

In this column are SEMs (2500× magnification) of the surface of a composite sample after 156,000 cycles of a 3-body wear test. See Wear Wheel Section, if desired, for more detailed description of the test methodology. Samples were not obtained from the same wheel. These photos may be indicative of the polish retention of restored occlusal surfaces.

Filtek P60 Restorative

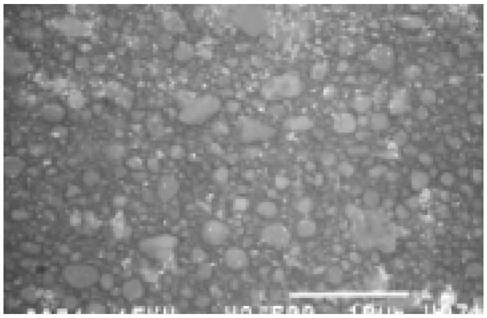


The 3M™ Filtek™ P60 Restorative filler consists of the same proprietary manufactured, rounded zirconia/silica particles as 3M™ Z100™ Restorative. The particle size distribution of Filtek P60 restorative is 0.01 to 3.5 µm. The average particle size is 0.6µm.

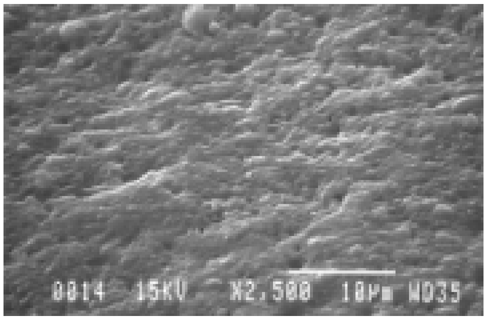


The surface of the Filtek P60 sample is irregular but not ditched or pitted from filler particle loss.

Z100 Restorative

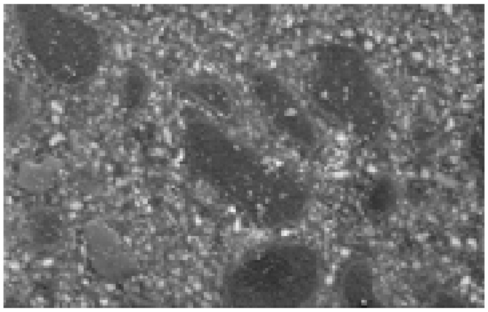


The manufactured proprietary Z100 restorative filler is composed of rounded zirconia/silica particles. The particle size distribution of Z100 restorative is 0.01 to 3.3µm. The average particle size is 0.6µm. The white splotches are artifiacts of the sample preparation.



The SEM of the sample surface after wear wheel abrasion of Z100 restorative confirms the similarities in the filler distribution between Z100 restorative and Filtek Z250.

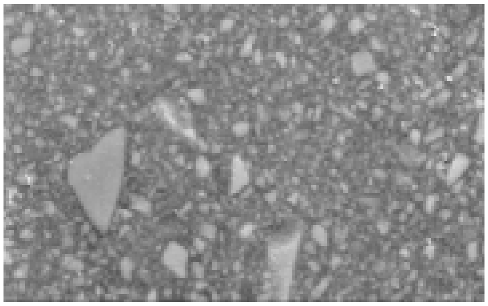
Solitaire Restorative



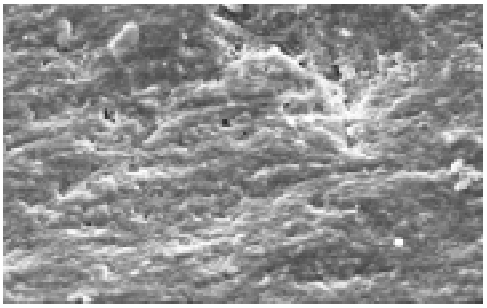
The product literature for Solitaire™ claims the filler loading (by weight) is 65%. The filler particle size range is from 2-20µm. the filler is proprietary and is claimed to be porous. The SEM shows the wide size range of filler particles.

The surface of Solitaire after abrasive wear is remarkably smooth given the particle size range. It appears that both resin matrix and filler are lost at a somewhat similar rate.

SureFil Restorative

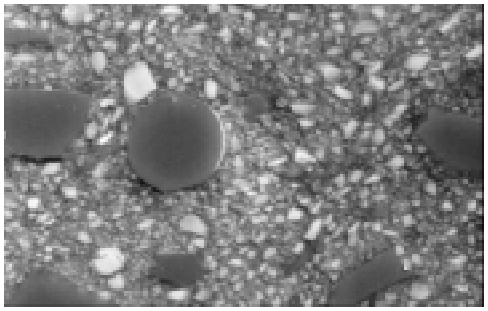


The filler particles in SureFil™ are similar in shape (jagged edges and irregular shaped) to TPH-Spectrum™ which is indicative of ground glass. Some of the particles are in excess of 10µm. The filler is composed of barium boron fluoroaluminosilicate glass and fumed silica. The filler loading is claimed to be 82% by weight.

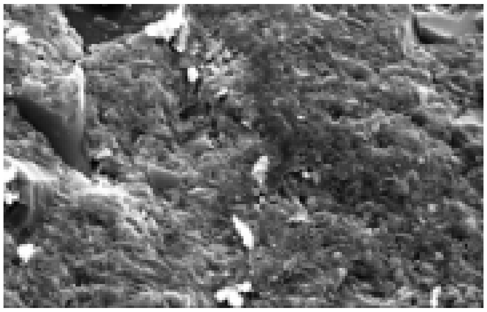


The surface of SureFil after abrasive wear shows the effect of resin matrix and filler particle loss (pits and divots).

ALERT Restorative



The filler in ALERT™ consists of a wide range of particle sizes and relatively large glass fibers. The glass fibers are irregularly shaped and some are over 75 µm long. the filler loading is claimed to be 84% by weight.



The surface of the ALERT sample after abrasive wear shows the effect of the filler composition. The jagged, irregular surface is indicative of filler particle (pits), fiber loss (divots) and fiber breakage during the test.

Technique

Cure Depth

As in any procedure, there is a strong desire by dentists to decrease the amount of time needed to place a composite restoration. Tedious curing techniques are often a disadvantage cited during posterior composite discussions. Light intensity, cure time and composite material (e.g., resin, filler, opacity, and shade) impact depth of cure.

There are two logical paths composite manufacturers can examine to try to reduce cure time. The first is to increase the increment depth. The second is to shorten the time that is required to cure an increment. Extensive testing was conducted to determine which path would provide the most benefit to the dentist. Much of this testing used the C2 shade of 3M™ Filtek™ P60 Posterior Restorative, as this is the most challenging shade to cure.

ISO 4049 Testing

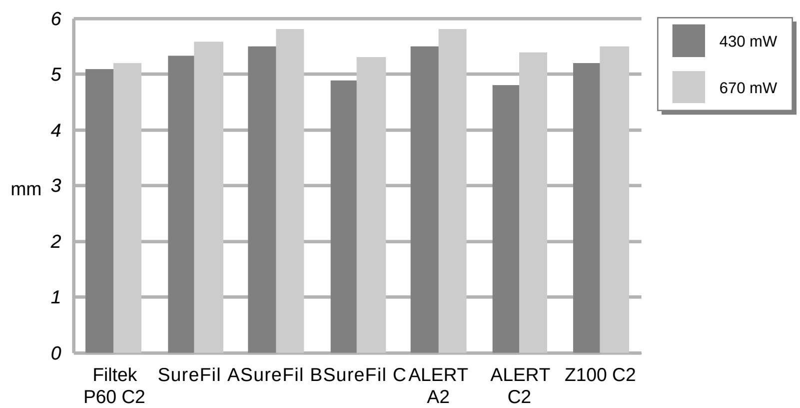
For some dental materials, there are standards that manufacturers must meet to sell these materials globally. These standards document a list of test protocols and results required to be considered a viable material. The general standard that applies to composites is ISO 4049.

Current ISO/DIS 4049:1988E Depth of Cure

This current standard details the following protocol to establish the depth of cure. A composite is packed into a metal cylinder. Top surface is exposed to a visible light source for the recommended length of time. After exposure, the composite is removed from the mold and uncured material is scraped away using a plastic instrument. The remaining cylinder is measured and the value recorded as the depth of cure.

The chart below shows the results of this test when using a light with a high (670mWatts/cm^2) or an adequate intensity (430mWatts/cm^2). All materials tested exhibited a greater than 4mm depth of cure.

*Figure 18.
Depth of Cure
ISO/DIS 4049: 1988E*

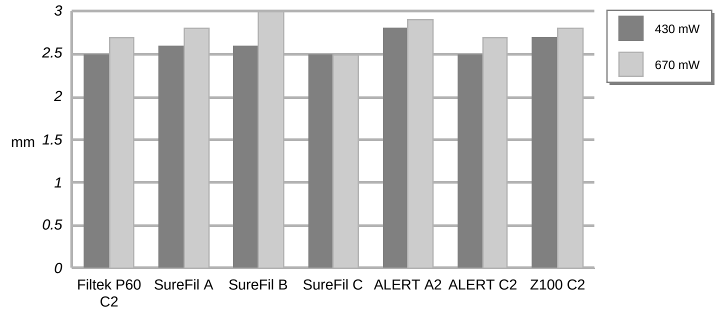


Draft ISO/DIS 4049:1998 Depth of Cure

This draft standard (scheduled to go into effect soon) has increased many of the requirements for composites, including depth of cure. The method used to test depth of cure in this draft standard is similar to the current standard with one notable exception. The value recorded is 1/2 of the length of the remaining cylinder of composite.

The chart below depicts the results of the new draft proposal. Note the values are roughly 1/2 the values obtained by following the current standard. No material tested, even using a high intensity light obtained a reportable depth of cure greater than 3mm.

Figure 19. Depth of Cure Draft ISO/DIS 4049:1998



Barcol Hardness

A cylinder of composite of a specific depth is light cured from the top of the sample. A Barcol Hardness tester is used to measure the sample hardness on the top and the bottom. If the material isn't cured completely, the two values will differ. In general, the greater the difference between the top and bottom Barcol values, the more incomplete the cure of the composite.

Samples 5mm thick were prepared of all of the materials except 3M™ Z100™ Restorative. A 2.5mm sample of Z100 restorative was used as a control in this study. All materials were cured for 40 seconds. Barcol Hardness was measured after 5 minutes. The chart below shows the differences in top vs. bottom Barcol Hardness values using visible-light curing units at acceptable but different intensities. As expected, the greatest differences occurred with the C2 shade (more yellow pigments) using an adequate intensity light.

Figure 20. Barcol Hardness (5mm) Light Intensity 430 mWatts/cm²

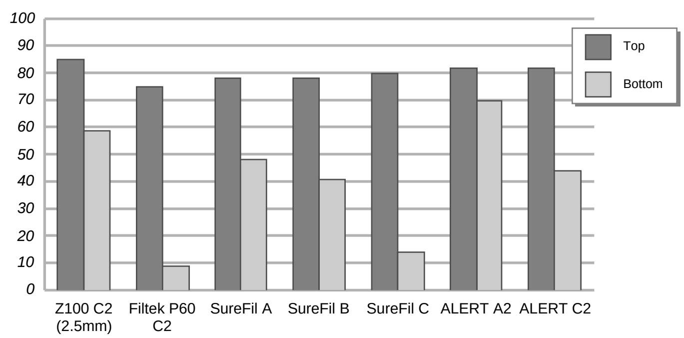
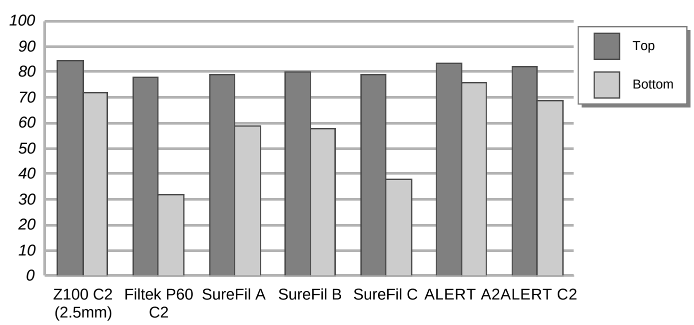


Figure 21. Barcol Hardness (5mm) Light Intensity 660 mWatts/cm²

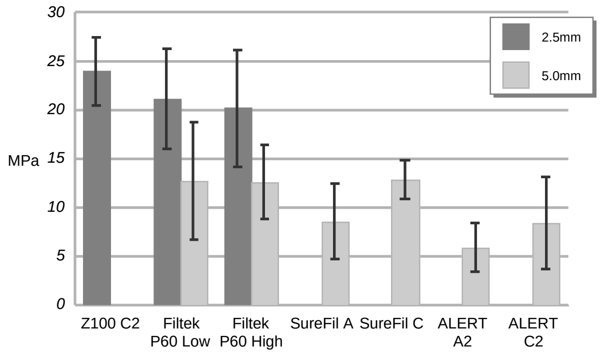


Bond Strength

If material at the bottom of the increment was undercured (not adequately polymerized), the bond strength might be affected. Shear bond strength to dentin was measured using a light with an adequate light intensity (430mW/cm²). For comparison purposes samples of 3M™ Filtek™ P60 Restorative were also cured with a high intensity light (>600mW/cm²).

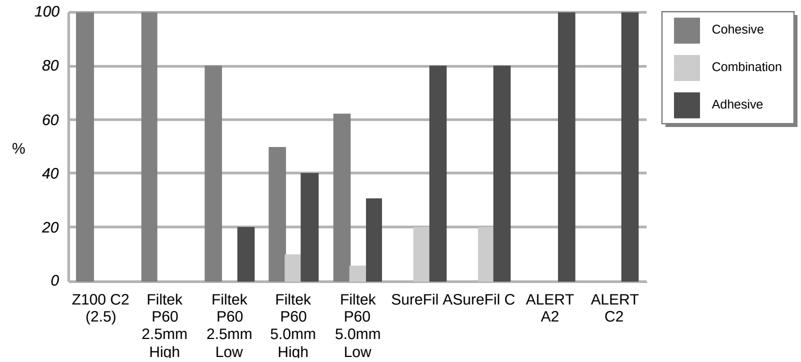
Samples were bonded to bovine dentin following manufacturer's instructions for bonding agent and composite placement technique. 3M™ Z100™ Restorative with 3M™ Single Bond Dental Adhesive System was used as a control. 3M™ Filtek™ P60 Posterior Restorative was bonded using Single Bond adhesive, ALERT™ with BOND-1® and SureFil™ was bonded with Prime & Bond 2.1™.

Figure 22. Bond Strength to Dentin



The bond strength of Filtek P60 restorative decreased by almost 50% when a 5mm increment was placed vs. a 2.5mm increment regardless of light intensity. The bond strengths of a 5mm increment of ALERT (A2 and C2 shades) and SureFil A shade were below 10MPa. Additionally, the bonds failed adhesively more often than the sample failed cohesively (the preferred method) when curing 5mm thick increments regardless of material tested.

Figure 23. Bond Failure Mode



Cure Depth Summary

The data from all of these test procedures indicate light penetration to the base of the thick increments is inadequate to properly polymerize the composite.

- There is a significant drop in Barcol Hardness values when comparing the top and bottom values for 5mm thick materials even with an adequate light intensity.
- The bond strengths of composites (i.e., SureFil and ALERT) cured at a 5mm depth were low.
  - This could be the result of the light not crosslinking the adhesive/composite interface, or
  - Partially polymerized and therefore weakened composite at the interface creating a weak area for bond failure to occur.
- Bond failure occurs adhesively using a 5mm increment of ALERT and SureFil. Bond failure occurs cohesively with a 2.5mm increment of Z100 restorative or Filtek P60 restorative bonded with Single Bond adhesive.

All of these data support the need for incremental placement and curing of current composite materials. Placing and curing two 2.5mm increments of Filtek P60 restorative require the same amount of cure time as a 5mm layer of ALERT or SureFil.

Technique Comparison

An additional technique comparison of 3M™ Filtek™ P60 Posterior Restorative, ALERT™, Solitaire™, SureFil™ and Ariston™ demonstrates that the relative speed of placing Filtek P60 restorative is actually faster than that for the other materials.

The placement techniques for posterior restorative materials are detailed in the tables below. In each case, manufacturers' instructions and recommendations were followed.

Filtek P60

		Seconds	
Pulp Protection			CaOH if pulp exposure. 3M Vitrebond Liner/Base recommended in deep areas of cavity.
Adhesive	*Etch*	15	
	Rinse	10	
	Blot	2	
	Apply 1st Coat Adhesive	5	
	Apply 2nd Coat Adhesive	5	
	Dry	2	
	Light Cure	10	
Composite for 5mm Depth	*Increment & Light Cure*	20	
	Increment & Light Cure	20	
Finish & Polish			
Total Time		89	

ALERT

		Seconds	
Pulp Protection			Not addressed
Adhesive	*Etch*	20	
	Rinse	10	
	Dry	2	
	Apply Adhesive	5	
	Apply Adhesive	5	
	Dry	10	
	Light Cure	10	
Liner	*Apply*	5	"Apply 0.5-1.0 mm Flow-It Flowable Composite to walls and floor of preparation…"
	Light Cure	40	
Composite for 5mm Depth	*Increment & Light Cure*	40	5 mm increment
Seal	*Etch*	20	"Acid etch ALERT Condensable Composite surfaces with…etchant and extend out to cover approximately 2mm of enamel adjacent to restoration margin."
	Rinse	15	
	Dry	10	
	Apply Seal	5	"Apply PROTECT-IT! Composite Surface Sealant with applicator provided. Be sure to cover entire restoration surface and the etched marginal area."
	Air Thin	5	
	Light Cure	20	
Finish & Polish			"Finishing/Polishing is usually unnecessary."
Total Time		**222**	

SureFil

		Seconds	
Pulp Protection			"In close proximity to the pulp, less than 1mm remaining dentin thickness, place a calcium hydroxide liner…"
Adhesive	*Etch*	15	
	Rinse	15	
	Blot	2	
	Apply Adhesive	20	"The surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime & Bond 2.1 Adhesive."
	Dry	5	
	Light Cure	10	
	Apply Adhesive	5	"Apply second application of Prime & Bond 2.1 Adhesive to all cavity surfaces. Immediately air dry 5 seconds to evaporate solvent, then place SureFil over the uncured Prime & Bond 2.1 Adhesive."
	Dry	5	
Composite for 5mm Depth	*Increment & Light Cure*	40	5mm Increment: "It is strongly recommended that the instrument used to contour cavosurface margins (occlusal and proximal) should be lubricated from time to time with a thin coat of residual Prime & Bond 2.1 to ensure optimal adaptation…Be sure the instrument is well lubricated with residual Prime & Bond 2.1 during the carving and contour process."
	Light Cure	30	"The composite should be additionally exposed to the curing unit through the proximal, lingual and buccal enamel walls following metal matrix removal."
Finish & Polish			
Total Time		**147**	

Solitaire

		Seconds	
Pulp Protection			"In profound cavities, dentin in proximity to pulp should be protected with an appropriate subfilling (e.g., calcium hydroxide compound and glass ionomer cement).
Adhesive	*Etch*	15	
	Rinse	15	
	Dry	2	
	Primer	30	"Apply Solid bond P, massaging it into the dentin…for 30 seconds" Used on exposed dentin.
	Dry	2	
	Apply Adhesive	5	"Introduce Solid bond S into the cavity…applying a uniform, thin layer to the etched enamel areas."
	Dry	2	
	Light Cure	40	
Composite for 5mm Depth	*Increment & Light Cure*	40	Increment depth of 2 mm.
	Increment & Light Cure	40	Increment depth of 2 mm.
	Increment & Light Cure	40	Increment depth of 2 mm.
Finish & Polish			
Total Time		**231**	

Ariston

		Seconds	
			Indicated for "Class I and II restorations in deciduous and permanent teeth with retentive cavity preparations" and "Amalgam substitute"
Pulp Protection	*Apply & Wait*	25	"Ariston Liner is used to seal the enamel and dentin and to generate a bond to the Ariston pHc restorative material."
	Air Thin	5	
	Light Cure	20	
Composite for 5mm Depth	*Increment & Light Cure*	40	"It is advisable to use at least two layers to restore cavities with proximal boxes. The first layer, which is placed on the bottom of the proximal box, should be at least 1-2 mm thick."
	Increment & Light Cure	40	3-4 mm increment. Recommended maximum increment depth is 4 mm.
	Increment & Light Cure		
Finish & Polish			
Total Time		**130**	

Summary

	Filtek™ P60	Z100™	ALERT™	SureFil™	Solitaire™	Ariston™
Pulp Protection						50
Liner						
Adhesive	49	49	62	77	111	
Liner			45			
Composite for 5mm depth	40	80	40	70	120	80
Seal			75			
Finish & Polish						
Total Time (seconds)	**89**	**129**	**222**	**147**	**231**	**130**

Instructions For Use

3M™ Filtek™ P60 Posterior Restorative

General

3M Filtek P60 Restorative material is a visible-light activated, radiopaque, restorative composite. It is designed for use in posterior restorations. The filler in Filtek P60 restorative is zirconia/silica. The inorganic filler loading is 61% by volume (without silane treatment) with a particle size range of 0.01 to 3.5 microns. Filtek P60 restorative contains BIS-GMA, UDMA and BIS-EMA resins. A 3M dental adhesive is used to permanently bond the restoration to the tooth structure. The restorative is available in a variety of shades. It is packaged in traditional syringes.

Indications

Filtek P60 restorative is indicated for use in:

- Direct posterior restorations
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Precautions

Filtek P60 restorative contains methacrylates A small percentage of the population is known to have an allergic response to acrylate resins. To reduce the risk of allergic response, minimize exposure to these materials. In particular, exposure to uncured resin should be avoided. **Use of protective gloves and a no-touch technique is recommended.** If restorative material contacts skin, wash immediately with soap and water. Acrylates may penetrate commonly used gloves. If restorative contacts glove, remove and discard glove, wash hands immediately with soap and water and then reglove. If accidental contact with eyes or prolonged contact with oral soft tissues occurs, flush immediately with large amounts of water.

Instructions for Use

I. Preliminary

A. Prophy: Teeth should be cleaned with pumice and water to remove surface stains.

B. Shade Selection: Before isolating the tooth, select the appropriate shade(s) of restorative material.

C. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used.

II. Posterior Restorations

A. Cavity Preparation: Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.

B. Pulp Protection: If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure, place a minimum amount of calcium hydroxide on the exposure followed by an application of 3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base. Vitrebond liner/base may also be used to base areas of deep cavity excavation. See Vitrebond liner/base instructions for details.

C. **Placement of Matrix:** Place a thin dead-soft metal, or a precontoured mylar or a precontoured metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.

D. **Adhesive System:** Follow the manufacturer's instructions regarding etching, priming, adhesive application and curing.

E. **Dispensing the Composite:** Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.

F. **Placement:**

1. Using a nonmetallic placement instrument, place restorative into the cavity in increments no thicker than 2.5mm.
   Placement hints:

   a) To aid in adaptation, the first 1mm layer may be placed and adapted to the proximal box.

   b) Avoid intense light in the working field.

   c) A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.

2. Light cure each increment 20 seconds by exposing its entire surface to a high intensity visible light source, such as a 3M curing light. Hold the light guide tip as close to the restorative as possible during light exposure.

3. **Slightly** overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.

G. **Finishing:** Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with 3M Finishing Strips.

H. **Adjust Occlusion:** Check occlusion with thin articulating paper. Centric and lateral excursion contacts should be examined. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.

I. **Polishing:** Polish with Sof-Lcx Discs and Strips or with white stones and rubber points where discs are not suitable.

III. 3M™ Filtek™ P60 Restorative Indirect Procedure for Inlays, Onlays Or Veneers

A. Dental Operatory Procedure

1. **Shade selection:** Choose the appropriate shade(s) of Filtek P60 Posterior Restorative prior to isolation.

2. **Preparation:** Prepare the tooth.

3. **Impressioning:** After preparation is complete, make an impression of the prepared tooth by following the manufacturer's instructions of the impressioning material chosen. Any 3M impressioning system may be used.

B. Laboratory Procedure

1. Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a "triple tray" type of impression was used.

2. Separate the cast from the impression after 45 to 60 minutes. Place pins in die and base the cast as for a typical crown and bridge procedure. Mount or articulate the cast to its counter model to an adequate articulator.

3. If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.

4. Section out the preparation with a laboratory saw and trim away excess or, expose the margins so they can be easily worked. Mark the margins with a red pencil if needed. *Add a spacer at this time if one is being used.*

5. Soak the die in water, then with a brush, apply a very thin coat of separating medium to the preparation, let it dry somewhat, then add another thin layer.

6. Add the first third of composite to the floor of the preparation, stay short of the margins, light cure for 20 seconds.

7. Add second third of composite. Allow for the last third (incisal) to include the contact areas, light cure for 20 seconds.

8. Place the die back into the articulated arch add the last third of composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured incisal increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process.

9. With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.

10. Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away cleanly from the cured restoration, until all of the restoration is recovered.

11. Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, then polish.

C. Dental Operatory Procedure

1. Roughen the interior surfaces of the indirect restoration.

2. Clean the prosthesis in a soap solution in an ultrasonic bath. Rinse thoroughly.

3. Cementation: Cement the prosthesis using a 3M resin cement system by following manufacturer's instructions.

IV. Storage and Use:

A. Do not expose restorative materials to elevated temperatures or intense light.

B. Unopened kits should be refrigerated (40^{o}F or 4^{o}C) to extend shelf life. Allow to come to room temperature for use.

C. Do not store materials in proximity to eugenol-containing products.

D. The composite pastes are designed for use at room temperature of approximately 21^{o}-24^{o}C or 70^{o}-75^{o}F. Shelf life at room temperature is 3 years.

V. Warranty

3M will replace product that is proven to be defective. **3M does not accept liability for any loss or damage, direct or consequential, arising out of the use or the inability to use these products.** Before using, the user shall determine the suitability of the product for its intended use and user assumes all risk and liability whatsoever in connection therewith.

Trademarks Cited

Coulter® is a trademark of Coulter Corporation. Ariston pHc™, Caulk®, Prime & Bond 2.1™, SureFil™ and Dentsply® are trademarks of Dentsply International. Charisma® and Solitaire™ are trademarks of Heraeus Kulzer, Inc. ALERT™, BOND-1®, Jeneric®, and Pentron® are trademarks of Jeneric Pentron. 3M™, Filtek™, P-10™, P-30™, P-50™, Scotchbond™, Visilux™, Vitrebond™ and Z100™ are trademarks of 3M.

3M

Dental Products Laboratory

3M Center, Building 260-2B-13
St. Paul, MN 55144-1000

Printed in U. S. A.