DENTSPLY

SCIENTIFIC
COMPENDIUM

SDR™
Smart Dentin Replacement

Marketed in US as:

SureFil® SDR™ flow
POSTERIOR BULK FILL FLOWABLE BASE

(For Individual Attention Only) 2011-08-15

With the compliments of

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1 Introduction

1.1 Product Description & Features

SDR™ Smart Dentin Replacement is a one-component, fluoride-containing, visible light cured, radiopaque resin composite restorative material. It is designed to be used as a base in Class I and II restorations. SDR™ material has handling characteristics typical of a “flowable” composite, but can be placed in 4 mm increments with minimal polymerization stress. SDR™ material has a self-leveling feature that allows intimate adaptation to the prepared cavity walls. Available in one universal shade, it is designed to be overlayed with a methacrylate based universal/posterior composite for replacing missing occlusal/facial enamel.

SDR™ material is used following application of a suitable dentin/enamel adhesive and is compatible with all DENTSPLY adhesives designed for use with visible light cured composite restoratives (See complete Directions for Use of selected adhesive). Use of other dentin/enamel adhesive systems with SDR™ material is at the discretion and sole responsibility of the dental practitioner.

SDR™ material is used in conjunction with a suitable universal/posterior restorative material as an occlusal/facial enamel replacement and is compatible with numerous restorative materials including DENTSPLY visible light cured methacrylate-based universal/posterior restorative materials designed for posterior Class I & II restorations.

While the features of SDR™ are described in this manual, a partial list is included below.

- Low Polymerization Shrinkage and Polymerization Stress
- Large increment basing of up to 4 mm thickness
- Optimized handling for easy placement and adaptability to cavity preparations
- Pre-dosed Compula® Tips for direct intra-oral application
- Chemically compatible with existing methacrylate based adhesives and composites
- Fluoride Containing glass filler

1.2 Research Development Background

A great deal of discussion has taken place around the polymerization shrinkage of composite restoratives in dental applications (Truffier-Boutry D, et al, 2006; Peutzfeldt A, 1997). Much of the discussion focused on attempts to reduce polymerization shrinkage in the thought that this reduction would have a beneficial effect on the restorative procedure. Among the desired outcomes of this reduction in shrinkage was improved marginal integrity, better adaptation to the cavity walls, reduced cusp deflection, etc. While it is worthy to attempt to reduce these clinically observable effects, perhaps too much emphasis was placed merely upon reduction of polymerization shrinkage alone. Rather, within the last several years, DENTSPLY Caulk has been focusing not simply on the amount of polymerization shrinkage, but the resultant effect of this process, namely, polymerization stress.

2 The SDR Technology Overview

2.1 Polymerization Shrinkage & Stress

<u>Background:</u> Visible light cured resin composites contain multifunctional, reactive molecules called monomers. When exposed to light, these monomers link together to create large molecules called polymers, which, in turn, link together to form a continuous network. The polymerization process requires that monomers physically move closer together to chemically react via a free radical process. This process results in a net loss of volume referred to as polymerization shrinkage if not restricted by e.g. bonding to a cavity. When this shrinkage process is restricted stress builds up in the material. In the initial stages of the polymerization, the monomers and small polymer chains easily dissipate stress since they are free to move and relieve stress. As more monomers react, the polymers link together to form a network. The point at which a network is formed is called the gel point. As the reaction continues, monomers and polymers continue to add to the network and eventually lose their ability to move. The material becomes rigid. This point is called the vitrification point. As the reaction continues, stress builds rapidly since stress cannot be dissipated by movement anymore. The material resists shrinkage and results in a force on the composite referred to as ***polymerization stress***. Not only will this ***polymerization stress*** be trapped within the composite itself, but it will also exert forces on bonded interfaces to which the composite is attached.

It is the transfer of ***polymerization stress*** to tooth structure that is the cause of many clinical problems. In a well bonded composite restoration, polymerization contraction stress is transferred through the interface with the tooth. This force on the tooth structure may result in enamel fracture, cuspal movement, and cracked cusps. The cavity design and its influence on the transfer of the developing polymerization stress are documented in the dental literature (Feilzer, AJ, et al. 1987). The term, “C-Factor” (Configuration-Factor) was used to describe this effect and relates the area of bonded surfaces to the area of un-bonded surfaces. As this ratio increases, the “C-Factor” increases, resulting in greater polymerization shrinkage stress on the bonded cavity walls. This relationship is demonstrated in Figure 1. It is apparent that Class I and II cavity designs have the highest C-Factors, making these types of restorations most susceptible to the effects of polymerization stress.

Class IV; C Factor 0.5 — **2 Bonded / 4 Un-Bonded**

Class III; C Factor 1 — **3 Bonded / 3 Un-Bonded**

Class II; C Factor 2 — **4 Bonded / 2 Un-Bonded**

Class I; C Factor 5 — **5 Bonded / 1 Un-Bonded**

Figure 1 As the area of bonded surfaces increase relative to unbonded surfaces, the C-factor increases. (Clinical pictures courtesy of Dr. Jeff Blank)

In less well bonded restorations, polymerization stress has the potential to initiate failure of the composite-tooth interface (adhesive failure) if the forces of polymerization stress exceed the bond strength. The resulting gap between the composite and cavity walls may produce post-operative sensitivity, microleakage, and/or secondary caries. If the bonding to the cavity walls is strong enough to avoid gap formation during polymerization, the stress concentrated inside the composite material can produce micro-cracks. As a result of this phenomenon, a restored tooth remains under stress even when there is no functional loading upon it. This implies a greater risk of failure during the tooth function. Therefore, if the magnitude of polymerization stress due to shrinkage can be reduced, the resulting effect on clinical success of composite systems may be improved.

Advantages of SDR™ Technology: Conventional dental composite materials are composed of reactive organic resins and mineral fillers. SDR™ differs from conventional resin by incorporating a Stress Decreasing Resin (SDR) technology. When a resin system is exposed to visible light, polymerization proceeds rapidly with concurrent volumetric shrinkage. With traditional resin systems, this rapid polymerization and shrinkage leads to a large increase in polymerization stress as shown in Figure 2. In contrast, with SDR™, under the same conditions, the increase in stress with time is greatly reduced. SDR™ resin provides an approximate 20% reduction in volumetric shrinkage and almost an 80% reduction in polymerization stress compared to a traditional resin system.

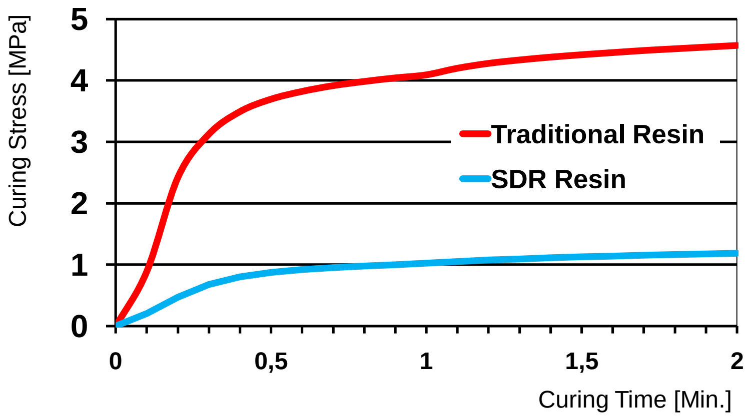

Figure 2 Polymerization Stress development for traditional methacrylate resin compared to SDR™ Resin Technology

The key note is the fact that curing rates and overall conversion are not sacrificed with SDR™. As shown in Figure 3, FTIR analysis of double bond conversion during curing of SDR resin and formulated SDR show very similar conversion rates to conventional resin and conventional composites such as Esthet•X flow.

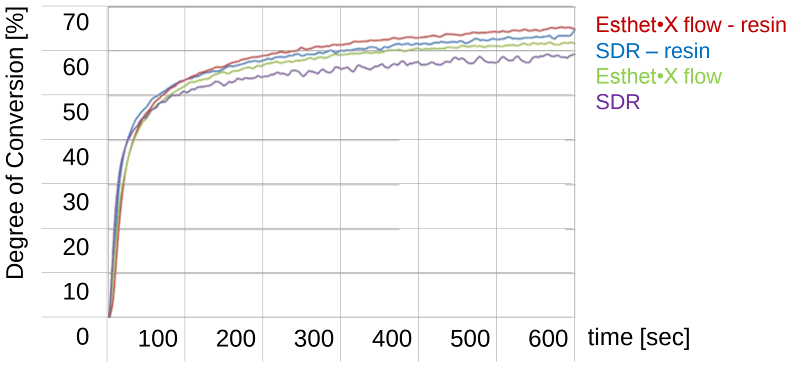

Figure 3 Degree of Double Bond Conversion vs. Time comparing neat resin or formulated product of Esthet•X flow to SDR™.

Further, the high degree of double bond conversion ensures the development of the physical and mechanical properties required for the use of SDR™ material as a posterior bulk fill flowable base. As shown in Figure 4, photo-rheology studies of the modulus development during curing illustrate the rapid network formation and strength development achieved with SDR™. The rate of modulus development of SDR™ is quite similar to a conventional flowable composite such as Esthet•X flow.

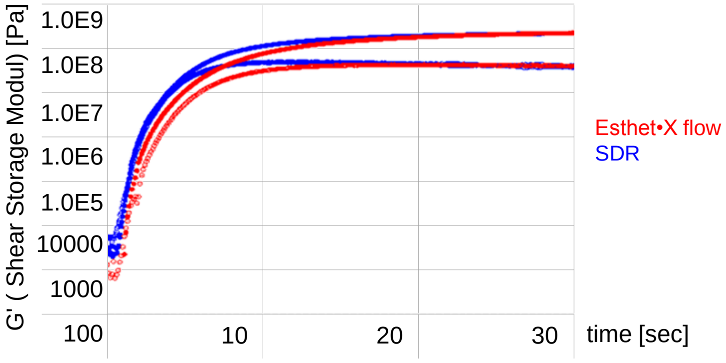

Figure 4 Storage Modulus Development vs. Time for Traditional Flowable (Esthet•X flow) compared to SDR™

2.2 Composition of SDR™

As shown in Table 1, the composition of SDR™ is a complex formulation of both conventional and novel components.

Ingredients:	Function:
• **SDR™ patented urethane di-methacrylate resin**	➢ **Low shrinkage, low stress structural resin**
• **Di-methacrylate resin**	➢ **Structural resin**
• **Di- functional diluents**	➢ **Crosslinking resin**
• **Barium and Strontium alumino-fluoro-silicate glasses (68% by wt., 45% by vol.)**	➢ **Fluoride structural glasses**
• **Photoinitiating System**	➢ **Visible light curing**
• **Colorants**	➢ **Universal Shade**

Table 1 The composition of SDR™ material comprises familiar and new components, each having specific functions in the overall composition

The novel SDR™ Resin technology (US Patents pending) is a urethane di-methacrylate structure that is responsible for the reduction in polymerization shrinkage and stress. SDR™ has very low overall shrinkage (3.5%) compared to other conventional flowable composites. Lower volumetric shrinkage contributes to overall lower shrinkage stress. This is due in part to the larger size of the SDR™ resin compared to conventional resin systems (molecular weight of 849 g/mol for SDR™ resin compared to 513 g/mol for Bis-GMA). The SDR™ Technology comprises the unique combination of such a large molecular structure with a chemical moiety called a “Polymerization Modulator” chemically embedded in the center of the polymerizable resin backbone of the SDR™ resin monomer (see Figure 5).

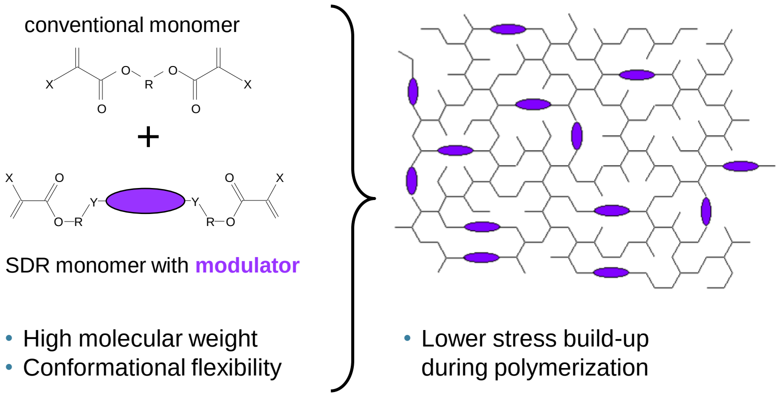

Figure 5 Chemistry of SDR™ Technology.

The high molecular weight and the conformational flexibility around the centered modulator impart optimized flexibility and network structure to SDR™ resin. Dynamic Mechanical Analysis (DMA) can be used to characterize visco-elastic materials. Figure 6 shows the tan Delta over temperature curve comparing SDR™ resin and SDR™ composite to Esthet•X flow and the respective neat resin after curing. The peaks in this graph represent the glass transition temperature (Tg). Both, SDR™ resin and SDR™ composite show not only a lower TG but also a higher tan Delta. Simplifying, the tan Delta expresses the ratio between dissipation (resulting from viscous behavior) and storage (resulting from elastic behavior) of energy induced into the material. Higher tan Delta is related to higher dissipation of induced energy. As a result SDR™ is able to dissipate more energy (and store less) when energy is induced e.g. during polymerization.

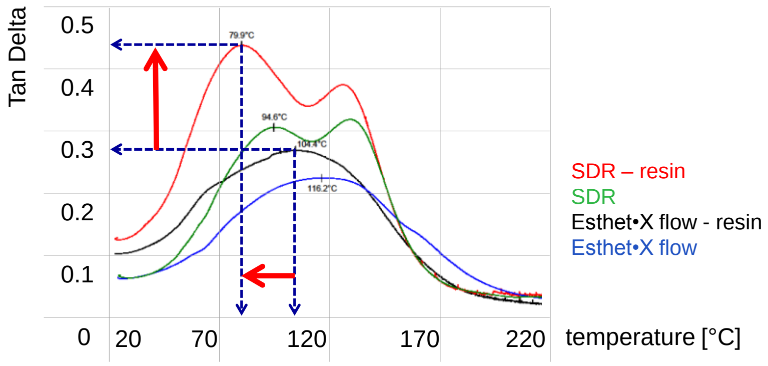

Figure 6 Tan Delta vs. Temperature from Dynamic Mechanical Analysis (DMA) for neat resin or formulated product comparing Esthet•X flow to SDR™

The methacrylate functional groups in the resin allow reaction to other typical methacrylate systems currently used in nearly all composite restorative materials. Thus, traditional total or self-etch methacrylate based adhesives will react with the SDR™ material via the same reaction as other traditional composite restoratives. The other polymerizable resins noted above are used in other DENTSPLY products, such as Esthet•X®HD Micro Matrix Restorative, TPH®3 Micro Matrix Restorative, etc. These resins provide structural reinforcement of the restorative, as well as strong crosslinking of the polymer network upon polymerization. The SDR™ formulation takes advantage of high glass filler loading (68% by weight, 45% by volume) to both decrease volumetric shrinkage and increase strength properties. The unique combination of fillers with SDR™ resin provides high depth of cure, and the proper rheology to achieve the unique self leveling characteristic for optimum adaptation and marginal integrity. The photoinitiator system, and the colorant are also trusted components used in other DENTSPLY restorative materials.

In summary, the unique structure of the Stress Decreasing Resin provides low stress to the composite system. The optimized balance of properties exhibited by SDR™ is a result of the combination of SDR™ resin with fillers and other formulation components. SDR™ combines these features to deliver the first posterior flowable base which can be bulk filled.

3 Indications for Use

SDR™ Smart Dentin Replacement is intended to be used as a:

- Base in cavity Class I & II direct restorations
- Liner under direct restorative materials – Class II box liner

SDR™ material is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins or any of its components.
(See Appendix A: Instructions for Use for more information.)

4 Clinically Relevant, *in-vitro* Physical Properties

The data presented in the following sections represents those *in-vitro* test procedures that are designed to closely approximate clinically relevant properties of the SDR™ material. All results for individual test results presented were performed in the same laboratories under identical conditions wherever possible. Thus, within each group of test results, comparison among products may be inferred. Caution should be applied when attempting to compare similar test results from different laboratories due to potentially different test conditions, parameters, etc. Where noted, accepted, standardized International Standards Organization (ISO) test methods were utilized when carrying out the testing. Please refer to the appropriate Appendices for a description of the test methodologies used for each respective property noted.

4.1 Polymerization Effects

4.1.1 Volumetric Shrinkage

The volumetric shrinkage of various flowable materials compared to SDR™ material is recorded in Figure 7.

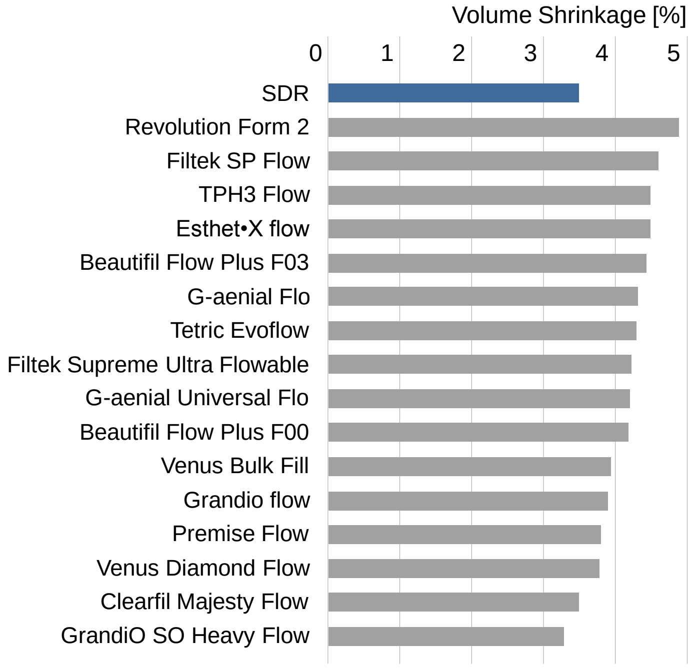

Figure 7 Volumetric Shrinkage of SDR™ material compared to other flowable materials

As can be noted from the results, the volumetric shrinkage of SDR™ material has been optimized to be lower than the majority of flowable materials. As discussed above, shrinkage observed on polymerization is a result of the chemical reaction of monomers and pre-polymers within the uncured composite reacting to visible light activation. The process of polymerization results in a net loss in volume which, if taken alone, would imply that the goal would be to reduce the shrinkage to as low a value as possible. On the other hand, ensuring maximum polymerization conversion implies that maximum shrinkage must occur in order to maximize the properties of the resulting polymer. Thus, this apparent conflict of minimizing shrinkage while maximizing conversion has been resolved with the SDR™ Technology through a reduction in the net polymerization stress that results from the shrinkage. Simply reducing the polymerization shrinkage without addressing the polymerization stress, that is the result of the shrinkage process, would be to overlook the root cause of the adverse effects observed in numerous clinical restorations. Thus, with SDR™, significant reduction in polymerization stress was the primary objective in designing a truly unique and ground breaking development, as discussed below.

4.1.2 Polymerization Stress

It is well recognized that the polymerization stress resulting from the polymerization shrinkage of composite restorations can lead to numerous adverse clinical effects, including de-bonding, post-operative sensitivity, marginal discrepancies, etc. (Yamazaki et al, 2006; Blaes 2008; Condon et al 2000; Ferracane 2008). The build-up of polymerization stress is a direct result of the polymerization shrinkage and constraint placed on the composite restoration. Constraint within the system is commonly a result of the bonded interfaces to which the composite restorative is attached. Thus, adhesive bonding of the composite restorative resists the contraction stresses during polymerization shrinkage which can cause stress to accumulate at the bonded interface and within the material. SDR™ was designed to mediate the polymerization reaction process so as to allow for low stress build-up when developing the polymer.

Several different methodologies were used to measure and record the polymerization stress developed upon light curing in different composite restorative materials (See Appendix for description of each method). Although each method uses differing techniques to observe the stress development, it can be noted that the overall results remain consistent; SDR™ demonstrated the lowest overall stress development of all materials evaluated.

4.1.2.1 National Institute of Standards and Technology (NIST) Tensometer Stress Method

(Echmiller FC, 2004; Lu H et al, 2004)

The NIST Tensometer (see Appendix 8.2.2) is an industry recognized method for direct measurement of polymerization stress within a composite material at the same time the measurement of the shrinkage of the system is occurring. Materials of varying viscosities and curing mechanism can be evaluated on the device, along with the relative degree of bonded to unbounded interfaces (e.g. “C-factor” [Feilzer AJ, et al, 1987]). The reduction in polymerization stress using the SDR™ technology compared to other composite flowable restoratives is presented in Figure 8. As can be observed from the data, the polymerization stress developed by SDR™ material is statistically significantly lower than all the traditional flowable materials evaluated. In addition, the polymerization stress of SDR™ material is significantly lower than any of the traditional Universal/Posterior composite restoratives recorded in Figure 9.

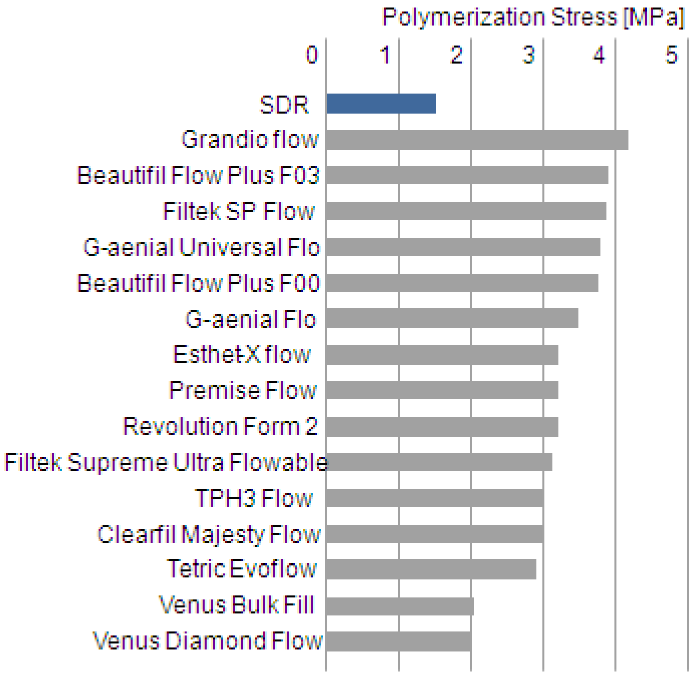

Figure 8 Polymerization Stress (NIST Tensometer) of SDR™ compared to other flowable materials

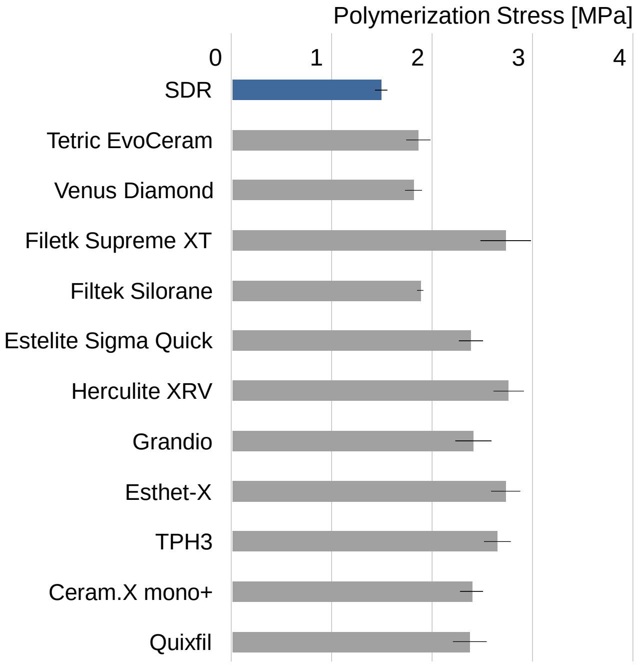

Figure 9 Polymerization Stress (NIST Tensometer) of SDR™ compared to other Universal/ Posterior Composite materials

4.1.2.2 Photoelastic Stress Method

The polymerization stress of SDR™ and several other materials was also evaluated using a photoelastic apparatus to record stress development during light curing (Ernst C-P et al 2009). A description of the methodology is shown in the diagram below and in the Appendix 8.2.3.

Specifically designed photoelastic materials having a lower photoelastic constant were prepared as holders for the tested polymerizing materials. The materials to be evaluated were bonded into the holders using a visible light curing device (See diagram at the left in Figure 10) and the photoelastic images recorded at 4 minutes and 24 hours post-curing. The resulting isochromatic rings allowed for visualizing the strain within the material. From the measured strain, stress values (MPa) were calculated. The results of the testing of SDR™ and other flowable materials are plotted in Figure 11 at t = 4 minutes and also 24 hours. Based on the results, the investigator provided conclusions regarding the stress developed in SDR™ material compared to other traditional flowable composites—see Table 2.

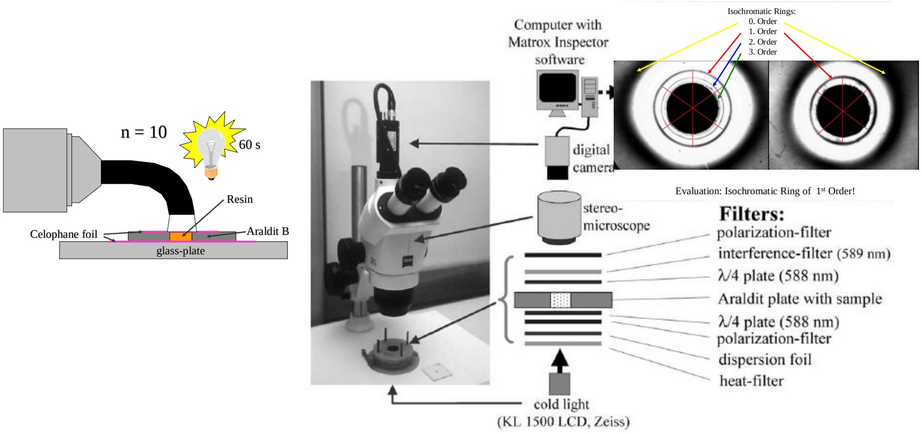

Figure 10 Polymerization Stress using Photoelastic stress methodology (Ernst CP, University of Mainz, Germany)

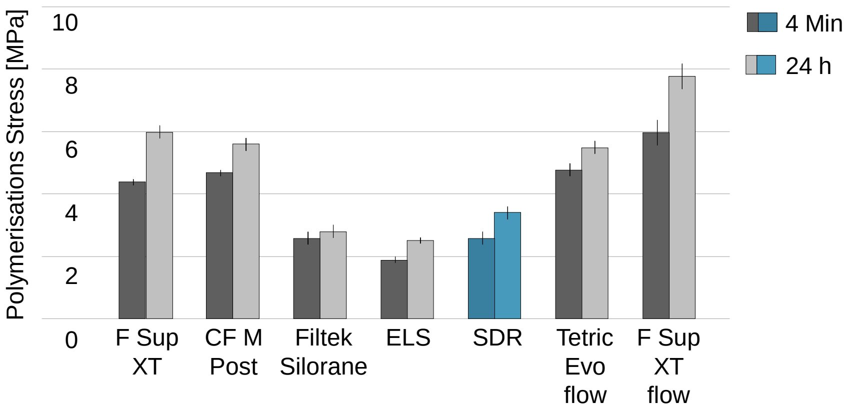

Figure 11 Polymerization Stress of SDR™ material compared to other Flowable materials, Composites, and "low shrinkage materials" using Photoelastic Stress methodology
(Ernst CP, 2009)

- ✓ **The shrinkage stress developed by SDR™ was significantly less than the shrinkage stress developed by Filtek Supreme Flow and Tetric EvoFlow.**
- ✓ **Surprisingly, the lower viscosity of SDR™ did not result in higher shrinkage stress data compared to all the other low shrinkage resin composites.**
- ✓ **Therefore, this material seems to have true clinical advantages in terms of handling properties, mainly in cavities with undercuts or smaller cavities, where often air bubbles are incorporated in more packable materials or generally materials with higher viscosity.**

Table 2 Polymerization Stress of SDR™ material – Conclusions
(Ernst CP, 2009)

4.1.2.3 Stress-Strain-Analyzer

Finally, the polymerization stress developed during the polymerization shrinkage of several materials was also measured using a Stress-Strain-Analyzer which continuously measured the contraction force generated by polymerizing the restorative material during light exposure, taking into account the compliance of the machine (Ilie N, 2007). The force generated was recorded in steps of 0.2 seconds for up to 300 seconds after start of polymerization, with each experiment conducted at room temperature and repeated ten (10) times for each material. Averaged curves of contraction force for different time spans are shown in Figure 12 to Figure 14.

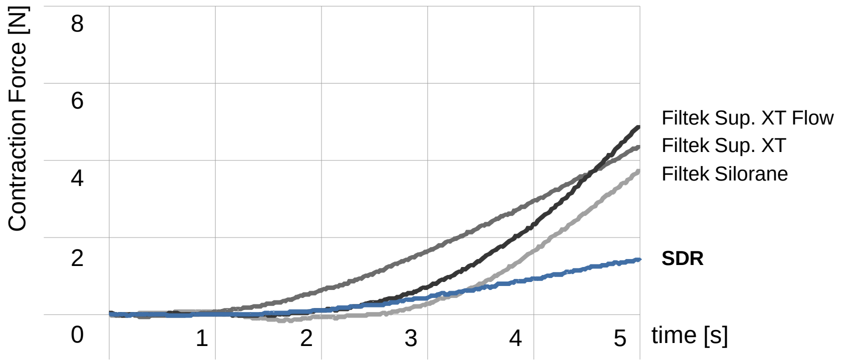

Figure 12 Averaged curves (mean of 10 runs) of contraction force within the first 5 seconds

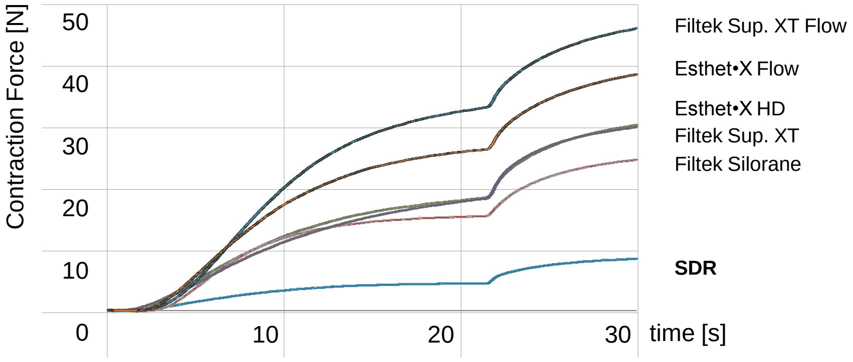

Figure 13 Averaged curves of contraction force within the first 30 seconds

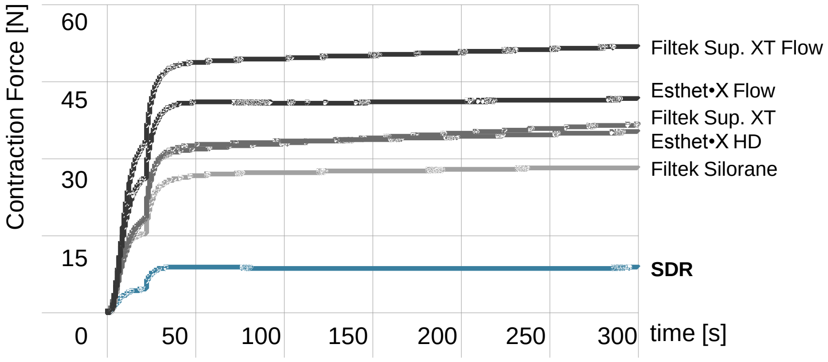

Figure 14 Averaged curves of contraction force up to 300 seconds

The polymerisation stress for SDR™ compared to two other flowable and universal composites, as well as Filtek Silorane are shown in Figure 15. A description of the methodology is presented in the Appendix 8.2.4.

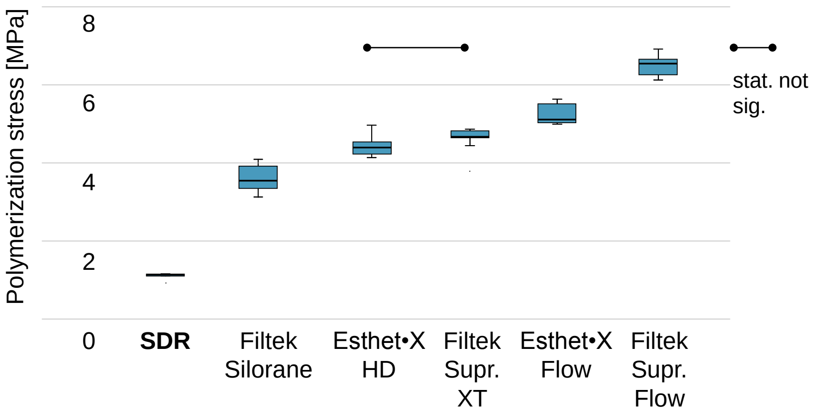

Figure 15 Polymerization Stress of SDR™ material using a Stress-Strain-Analyzer (Ilie N, Academy of Dental Materials 2009 #10)

As can be seen from the Stress-Strain-Analyzer, the results show SDR™ having the lowest overall stress developed and are in good agreement with the other two test procedures performed independently.

4.1.3 Curing Effectiveness

4.1.3.1 Depth of Cure: ISO 4049

The depth of cure for various flowable restoratives was measured following the procedure described in ISO 4049:2009(E). The restorative material was light cured for 20 seconds in a stainless steel mold with a cylindrical chamber, 4 mm in diameter and 8 mm deep (10 mm deep for SDR™) with a Whatman No. 1 filter paper as background using a Spectrum 800 halogen light at a light intensity of 500-550 mW/cm^2. The uncured underside was scraped away using a plastic spatula and the thickness of the remaining, cured composite was measured using a micrometer. The depth of cure was determined to be equivalent to the remaining thickness of material divided by two. The depth of cure as measured by ISO 4049 is shown below in Figure 16.

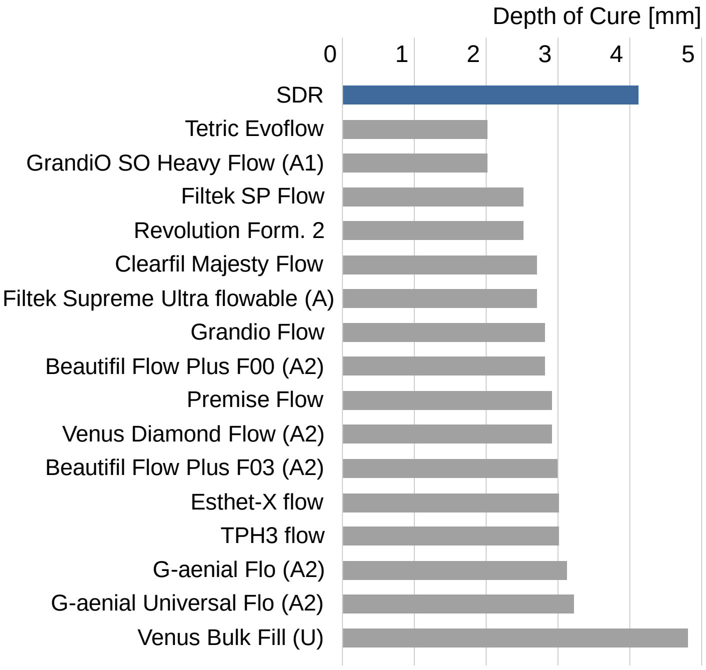

Figure 16 Depth of Cure (ISO 4049) of SDR™ flow material compared to other flowable materials, 20 second irradiation

As noted from the results, the depth of cure of SDR™ material exceeded all other flowable materials by about 1 mm to over 2 mm except Venus Bulk Fill. It should be noted that the ISO test described is a reasonable approximation to curing within composite materials. However, in order to ensure that the SDR™ material was completely cured throughout the 4 mm increment recommended, additional, more discriminating tests were performed and described as follows.

4.1.3.2 Degree of Conversion

With the recommendation for curing the SDR™ material in increments of 4 mm, it was essential to not only establish the low polymerization stress as noted above, but it was also critical to establish that the material had effective curing throughout a 4 mm increment. Thus, in addition to ISO depth of cure measurements, experiments were conducted to evaluate the degree of conversion of SDR™ material versus the thickness of material cured. The degree of conversion represents the extent to which the monomers are converted into polymer for the composite restorative material. The degree of conversion was measured using Attenuated Total Reflectance (ATR)-Near Infrared analysis (NIR). The degree of conversion for a methacrylate based restorative is typically on the order of 50 to 70%. Degree of Conversion higher that

70% for these filled restorative systems is **not** obtained due to inability for all the methacrylate portions of the molecules to react completely, but this does **not** imply inferior curing.

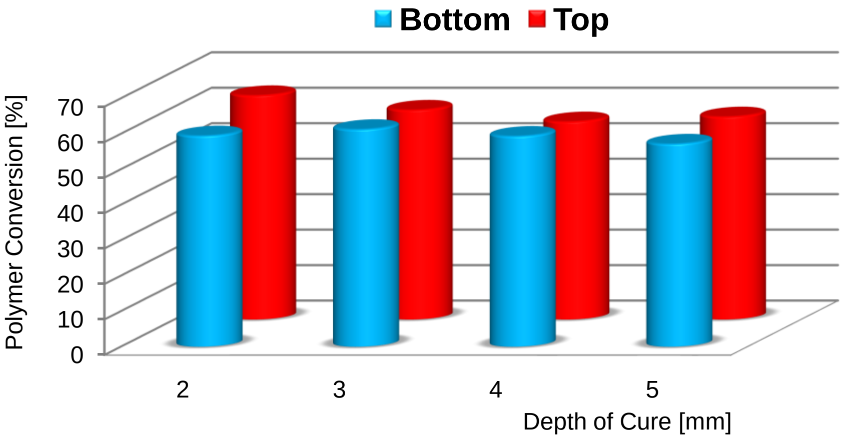

Figure 17 Degree of Conversion (%) of SDR™ material at varying thickness of cured material. (20 seconds curing time, NIR Analysis)

The graph in Figure 17 represents the degree of conversion (%) at the top of a cured specimen of SDR™ material (nearest the curing light) and the conversion (%) at the bottom of a cured specimen of 2 mm, 3 mm, 4 mm, and 5 mm, respectively. The degree of conversion at both the top surface, as well as the bottom surface, is nearly equivalent, confirming the excellent conversion of the SDR™ material even up to 5 mm. This is a key property that demonstrates acceptable conversion with the high depth of cure recommended for SDR™ material. This, along with the low stress, is one of the enabling properties that differentiate SDR™ material from other flowables.

This measurement of degree of conversion was also independently confirmed using a similar methodology (Reis A, 2009). In this study, several flowable restoratives, as well as one restorative material, were measured for degree of conversion versus thickness of the specimen. While the absolute values are slightly lower using this method to determine degree of conversion, the results for SDR™ material are very consistent with the ATR-NIR results above. The degree of conversion at various depths was plotted in Figure 18.

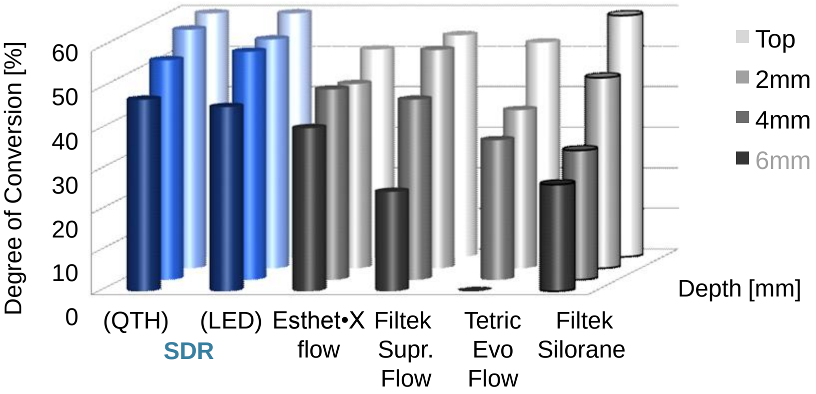

Figure 18 Degree of Conversion (%) versus depth of cure for 20 seconds by FTIR Analysis. (Note: Filtek Silorane cured 40 seconds)
(Reis A, Univ. of Guarulhos, SP Brazil)

As can be seen from the results, the degree of conversion versus depth of different materials varied considerably. One material (Tetric EvoFlow, Ivoclar-Vivadent) recorded no measurable conversion at 6 mm. The considerably lower degree of conversion versus depth for traditional flowables confirms that these materials should only be placed in 1 to 2 mm increments. Again, SDR™ material demonstrated very good conversions even to a depth of 6 mm from the light source, confirming bulk placements up to 4 mm as recommended. Also note that the results for curing using a quartz halogen (QTH) light were essentially equivalent to curing using a LED device (Column 1 and 2 respectively in Figure 18).

4.1.3.3 Knoop Hardness

The Knoop Hardness was measured for a number of flowable composite restorative materials versus SDR™ material*.* The ratio (%) of the Knoop hardness at the top surface versus the Knoop Hardness at the bottom of a predetermined thickness of material (2, 3, 4, and 5 mm) was then determined. A higher percentage ratio of the bottom to top hardness values indicates a more effective curing efficiency through the material. Typically, a value of 80 % (bottom to top) is considered to be effectively cured. As can be noted from Figure 19, the % ratio of Knoop Hardness bottom to top at 2 mm is nearly 100% for all materials as expected, with the notable exception of one material (Tetric EvoFlow, Ivoclar-Vivadent). However, for increasing thicknesses of material, the % bottom to top ratio drops rapidly, except for SDR™ material, which maintains a high % bottom to top ratio even through 5 mm thickness. These results further confirm the curing effectiveness of the SDR™ material and support the claim of 4 mm bulk curing.

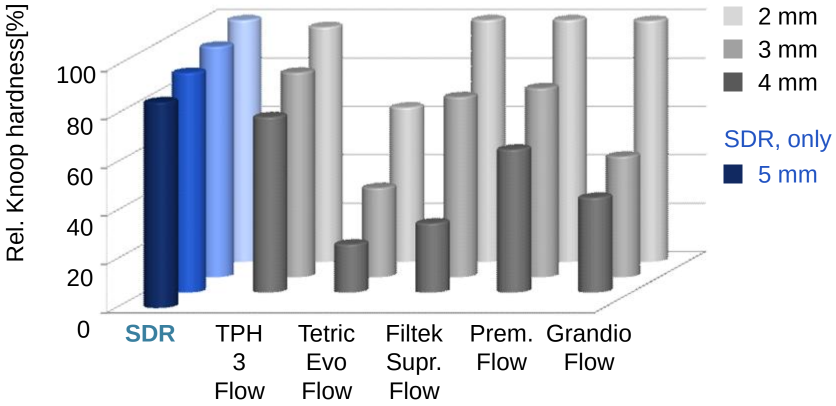

Figure 19 Ratio (%) of the Bottom Knoop Hardness to Top Knoop Hardness at varying thickness of material cured 20 seconds

4.1.3.4 Barcol Hardness

The hardness values for cured specimens were also measured using another hardness device known as a Barcol Impresser Tester. Similar to Knoop hardness results, the curing superiority of the SDR™ material compared to other flowables is demonstrated in Figure 20.

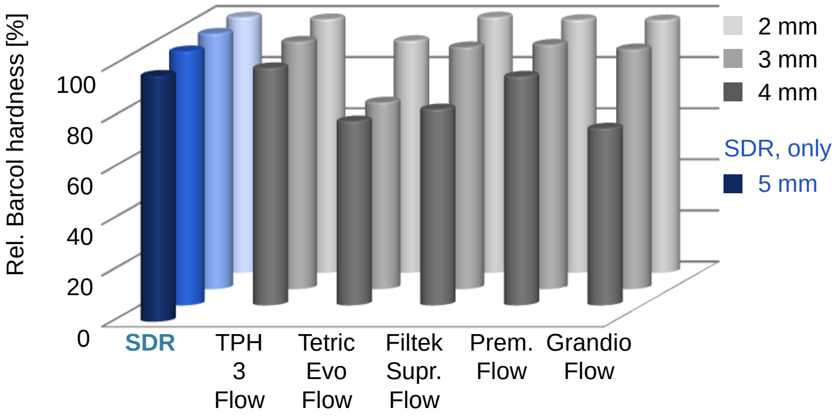

Figure 20 Ratio (%) of the Bottom Barcol Hardness to Top Barcol Hardness at varying thickness of material cured 20 seconds

4.2 Adhesion & Adaptation

4.2.1 Enamel & Dentin Bonding

The enamel and dentin bond strengths of SDR™ material were measured and compared to the bond strengths of Esthet•X® *flow* liquid micro hybrid using an Ultradent testing apparatus. The bonding agents used for testing were the conventional, methacrylate based adhesives, Prime & Bond® *NT*™ total etch and Xeno® IV Light Cured Self-Etching dental adhesives. As can be noted from Figure 21 below, the bond strengths of the SDR™ material are equivalent to those of the conventional resin system used in Esthet•X® *flow* liquid micro hybrid, confirming the complete compatibility with current methacrylate based adhesives.

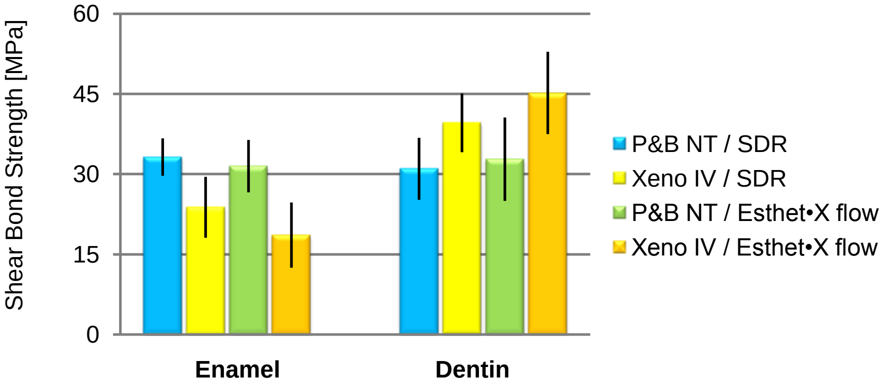

Figure 21 Adhesive bond strength to human enamel & dentin using SDR™ material and Esthet•X® flow

4.2.2 Class I Micro-tensile Bond Strength

Dr. Andre F. Reis

The purpose of this study was to evaluate the micro-tensile bond strength at the pulpal floor of Class I cavities restored with SDR™ material and Esthet•X®HD composite, another flowable/universal composite material and the Filtek Silorane system. The results are shown in Figure 22.

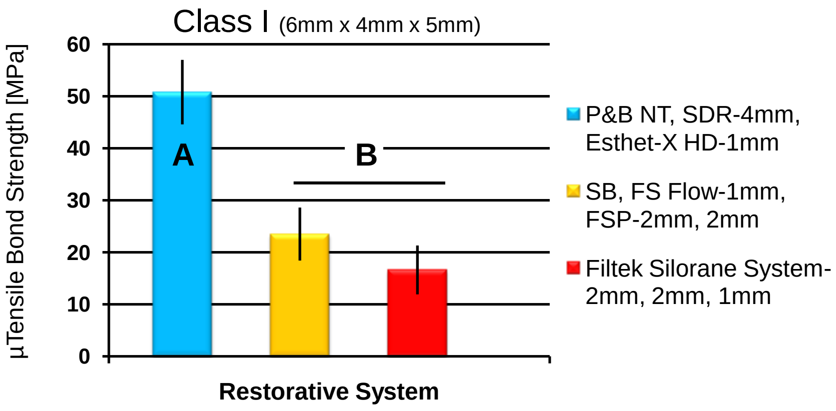

Figure 22 Micro-tensile bond strengths to human dentin restored in Class I cavities (Reis A, Univ. of Guarulhos, SP Brazil)

Freshly extracted human third molars were used in this study. Five teeth were used for each experimental group (N=5). After disinfection and removal of soft tissues a standardized Class I occlusal preparation (6 mm long X 4 mm wide X 5 mm deep) was made in each tooth using coarse diamond burs operated in a high-speed hand-piece using copious air-water spray.

Prepared teeth were randomly assigned to groups according to each restoration protocol. The adhesive material(s) were applied according to the recommended manufacturer’s directions. In the experiments using SDR™ material, the flowable material was placed in 4 mm bulk increments and light cured for 20 seconds. An occlusal layer of approximately 1 to 1 mm of Esthet•X® HD composite was incrementally added to build the final anatomy of the teeth. In the group using Filtek Supreme Flow, a 1 mm layer was applied and light cured for 20 seconds, followed by incrementally placing 2, ~ 2 mm oblique layers of Filtek Supreme XT and light curing for 20 seconds per increment. After placing Filtek Silorane Self-Etch Primer and Bond according to the manufacturer’s directions, Filtek Silorane was placed incrementally using the horizontal layering technique (increments of approximately 2 mm were used). Each increment was cured for 40 seconds.

Following restorative procedures, the specimens were placed in water for 24 hours prior to testing. The restored teeth were sectioned in a bucco-lingual direction into approximately 0.8 mm thick slabs with a diamond saw under water lubrication (Isomet 1000, Buehler). Four or five slabs were obtained from each tooth.

Each slab was trimmed from both sides with an extra-fine diamond bur to reduce the cross-sectional area at the interface of the pulpal wall to approximately 1 mm^2. Bonded specimens were tested in tension with a universal testing machine (EZ Test, Shimadzu) using a Ciucchi's jig at a crosshead speed of 1 mm/min. The µ-TBS values were expressed in MPa, which was calculated by dividing the peak break by the cross-sectional area of the bonded interface. Data were statistically analyzed by one-way ANOVA and Tukey test at the 5% confidence level.

As noted in Figure 22, the micro-tensile bond strength of Prime & Bond® *NT*™ in combination with SDR™ material and Esthe•X® HD composite provided statistically significantly higher results than the other three systems, which were in themselves, not statistically different. In addition, it should be noted that less steps were required to complete the SDR™ material Esthet•X® HD composite restorations as compared to either the flowable/universal restorative or the posterior restorative systems.

4.3 Microleakage & Marginal Integrity

Dr. Andre F. Reis, Guarulhos, SP Brazil

4.3.1 Class I Restorations; Microleakage

The purpose of this study was to evaluate the microleakage around Class I cavities restored with SDR™ material and Esthet•X® HD composite, another flowable/universal composite material and one posterior restorative. The results are shown in Figure 23.

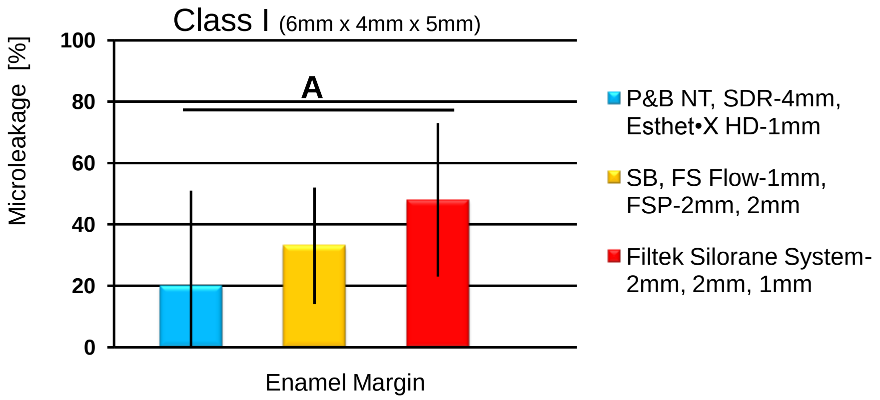

Figure 23 Microleakage on extracted human teeth using standardized Class I occlusal preparations. Specimens were stored 24 hours in water.
(Reis A, Univ. of Guarulhos, SP Brazil)

The methodology used to prepare the cavities and restorative procedures were identical to the methodology described in Section 4.2.2 above. After the restorative procedures, teeth were placed in water for 24 hours prior to testing. Restored teeth were coated with 2 layers of nail varnish applied up to within 1 mm of the bonded interfaces. In order to avoid desiccation artifacts, they were immersed in distilled water for 20 min prior to immersion in the tracer solution for 24 hours. Ammoniacal silver nitrate was prepared according to the protocol previously described (Tay et al, 2002). Tooth slabs were placed in the tracer solution in total darkness for 24 hours, rinsed thoroughly in distilled water, and immersed in photo-developing solution for 8 hours under a fluorescent light to reduce silver ions into metallic silver grains within gaps along the interface. The teeth were subsequently rinsed under running water to remove external dye. The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into three parts. The degree of dye penetration was then recorded (in mm) for each one of the slabs and a mean value was obtained for each tooth. Dye infiltration was expressed as a percentage of the total area of the cavity. Microleakage values were statistically analyzed by One-way ANOVA and Tukey test at the 5% confidence level.

As noted in Figure 23, the microleakage of Prime & Bond® *NT*™ adhesive in combination with SDR™ material and Esthet•X® HD composite, trended lower than other systems, though not statistically significant, and was restored in fewer steps with shorter curing times, thus reducing the overall time to complete the restoration.

4.3.2 Class I Restorations – Internal Cavity Adaptation

The purpose of this study was to evaluate the extension of internal cavity adaptation around Class I cavities restored with SDR™ material and Esthet•X® HD composite, another flowable/universal composite material and one posterior restorative. The results are shown in Figure 24.

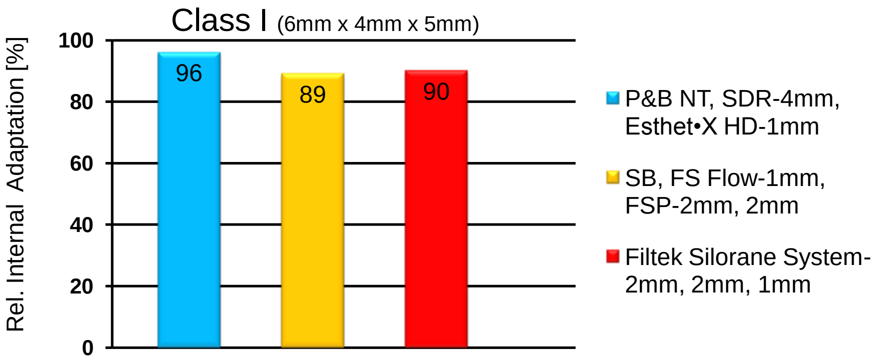

Figure 24 In-vitro Cavity Adaptation of restored Class I cavities using SDR™ material and other systems
(Reis A, Univ. of Guarulhos, SP Brazil)

Samples were prepared as described in Section 4.3.1 (Microleakage). After restorative procedures teeth were placed in water for 24 hours. The specimens were then sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into three parts. The central slab in each tooth was selected for gap formation analysis using a replica technique. Slabs were embedded in epoxy resin and then finished with 400, 600, 1000 and 2000-grit SiC paper under water and then polished with 6, 3, 1 and 0.25 µm diamond paste using a polish cloth. An impression of the specimens was taken using a PVS impression material and replicas were made with epoxy resin (Epoxycure, Buehler). Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of gaps was determined (in mm) using an image analysis software (Image J, NIH). Gap extension was expressed as a percentage of the total cavity contour. Results were statistically analyzed by ANOVA.

As noted in Figure 24, the internal cavity adaptation of Prime & Bond® *NT*™ adhesive in combination with SDR™ material and Esthet•X® HD composite was nearly perfect, taking note that the SDR™ material was placed in a bulk (4 mm) increments. Curing time for the SDR™ material/Esthet•X® HD composite combination was also considerably shorter than that for the other systems.

4.3.3 Class II Restorations – Marginal Integrity

The purpose of this study was to evaluate the marginal integrity of Class II cavities restored with SDR™ material and Esthet•X® HD composite. Another flowable/universal composite material restored by two different procedures was also included in the study.

Freshly extracted human third molars were used in this study. Five teeth were used for each experimental group (N=5). After disinfection and removal of soft tissue, a standardized MOD preparation was made in each tooth using a coarse diamond bur operated in a high-speed hand-piece using copious air-water spray. The margin of the mesial proximal box was placed in dentin (1 mm apical to the CEJ) and the distal margin was placed in enamel (1 mm coronal to the CEJ). Prepared teeth were randomly assigned to groups according to each restoration protocol. The prepared teeth were mounted in a jig featuring artificial training teeth that served as adjacent teeth. A contoured matrix band was placed around the teeth for restorative procedures.

The adhesive (either Prime & Bond® *NT*™ adhesive or Scotchbond 1 XT) material was applied according to the recommended manufacturer's directions. In the experiments using Prime & Bond® *NT*™/SDR™ material, the flowable material was placed in 4 mm bulk increments and light cured for 20 seconds. An occlusal layer of approximately 1 to 1 mm of Esthet-X® HD composite was incrementally added to build the final anatomy of the teeth. In the group using Filtek Supreme Flow, after application of Scotchbond 1 XT, a 1 mm layer was of the flowable material was applied and light cured for 20 seconds, followed by incrementally placing ~ 2 mm oblique layers of Filtek Supreme XT and light curing for 20 seconds per increment, according to the manufacturer's directions. In a third, experimental group, the adhesive application was performed per manufacturer's instructions, followed by a 4 mm bulk placement of Filtek Supreme Plus Flowable and light curing for 20 seconds. An occlusal layer of approximately 1 mm of Filtek Supreme Plus was incrementally added to build the final anatomy of the teeth, with each increment cured for 20 seconds.

(Note: This final procedure is **not recommended by the manufacturer**, but was performed to evaluate bulk placement performance of a flowable material with higher shrinkage and polymerization stress.)

After restorative procedures, an impression of the proximal boxes of each specimen was made with a VPS material (Aquasil Ultra XLV) and replicas were made using epoxy resin (Epoxycure, Buehler) for SEM evaluations of the marginal integrity. Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of marginal defects was determined (in mm) using an image analysis software (Image J, NIH). Results, expressed as a percentage of total marginal lengths, were expressed as a %. The summary data is presented in Figure 25.

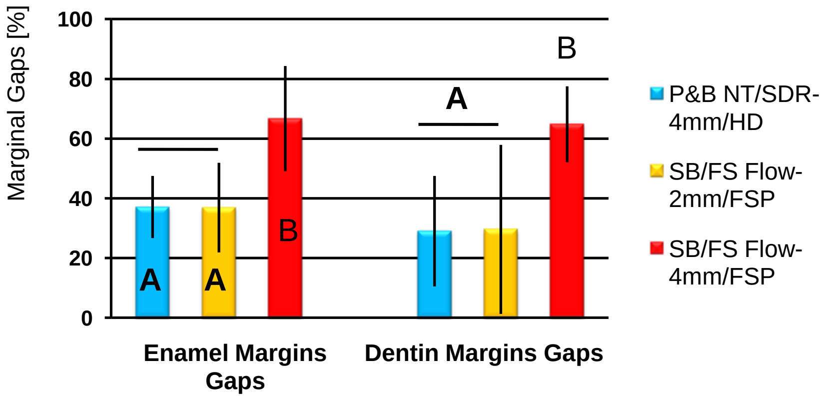

Figure 25 Marginal Integrity of restored Class II cavities using SDR™ material and other systems
(Reis A, Univ. of Guarulhos, SP Brazil)

The results of this evaluation confirm that the bulk (4 mm) placement of SDR™ material in combination with Esthet•X® HD composite performs statistically equivalent to that of the traditional, incrementally placed, 1 mm of flowable with universal composite. The experimental group also confirms that bulk placement of a traditional flowable material leads to statistically poorer results, presumably due to the higher shrinkage and polymerization stress of the traditional flowable material.

4.3.4 Class II Restorations: Marginal Integrity after chewing simulation

Prof. Roland Frankenberger, Marburg, Germany

In this study, MOD restorations in human teeth were evaluated for marginal integrity after simulated chewing conditions. The conditions of the tests (as summarized in Figure 26) included thermal cycling for 2500 cycles between 5 and 55°C, followed by 100,000 cycles in an in vitro chewing device with 50 N of force applied for each cycle. Upon completion of the testing, the teeth were evaluated for marginal integrity (and internal adaptation in a second study) using Scanning Electron Microscopy (SEM), and the percentage of perfect margins was determined.

- Materials & Method
  - n = 8 mod (box in Dentin or enamel)
- Storage & Stressing
  - 21 days at 37°C
  - 2 500 TC 5-55°C for 30 seconds
  - 100 000 cycles with 50 N
- Evaluation
  - SEM
    - margins
    - internal adaptation

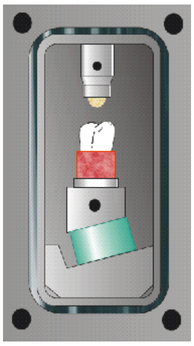

Figure 26 Protocol for in vitro cyclic fatigue of Class II restorations

In the first study, the Class II restoration tested included a 4 mm bulk placement of SDR™ material, followed by Esthet•X® HD composite as capping material which was compared to a control of Ceram•X™ nano ceramic composite applied in conventional incremental layering technique.

As depicted in Figure 27, the percentage of perfect margins in both enamel and dentin, before and after thermo-mechanical loading (TML) were equivalent for both test groups. Thus, the bulk placement of the SDR™ material in combination with Esthet•X® HD composite produced the same degree of perfect margins as Ceram•X™ nano ceramic composite under the condition of the test procedure.

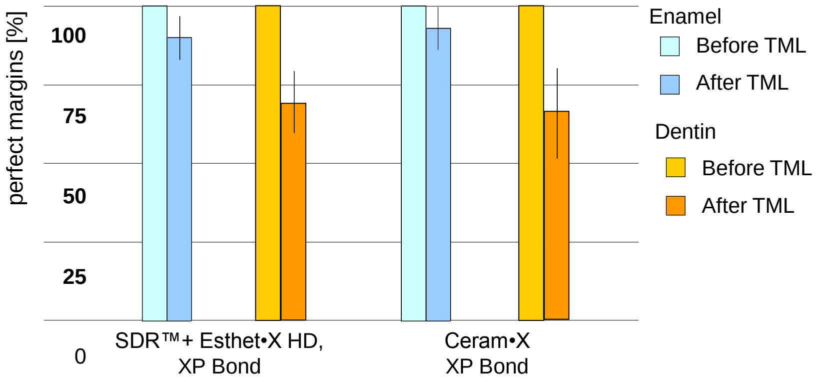

Figure 27 Results for percentage of perfect margins via in vitro cyclic fatigue of Class II restorations

In a second study, two Etch&Rinse and three SelfEtch adhesive restorative systems were investigated regarding a possible influence of SDR used in 4 mm as dentin replacement.

Therefore, in one group restorations were placed using the proprietary adhesive and composite within each system applying conventional incremental layering technique. In the second group still the same adhesive was used but SDR was placed in 4 mm as a first increment and capped with the respective composite of each system. Figure 28 to Figure 32 show the comparison of all groups tested. The conclusion by the investigator was:

> *“The present study revealed that the combination of SDR with the chosen five resin composites apparently shows equivalent adhesive performance in terms of marginal quality to enamel and dentin as well as internal dentin adaptation.”*

4.3.4.1 Marginal Integrity and Internal Adaptation – Etch&Rinse Adhesives

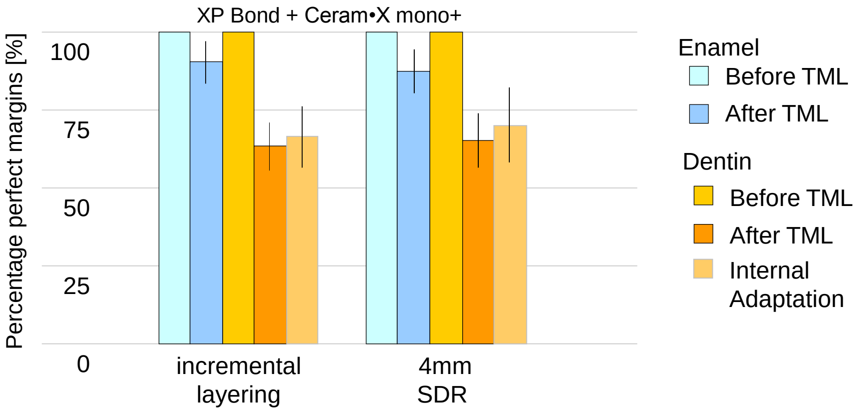

Figure 28 Percentage of perfect margins and internal adaptation before and after thermomechanical loading comparing incremental layering technique to SDR XP BOND + Ceram•X mono+

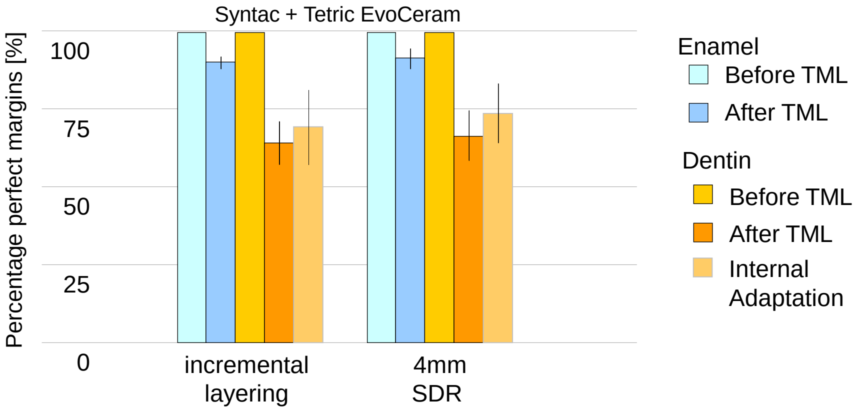

Figure 29 Percentage of perfect margins and internal adaptation before and after thermomechanical loading comparing incremental layering technique to SDR Syntac + Tetric EvoCeram

4.3.4.2 Marginal Integrity and Internal Adaptation – SelfEtch Adhesives

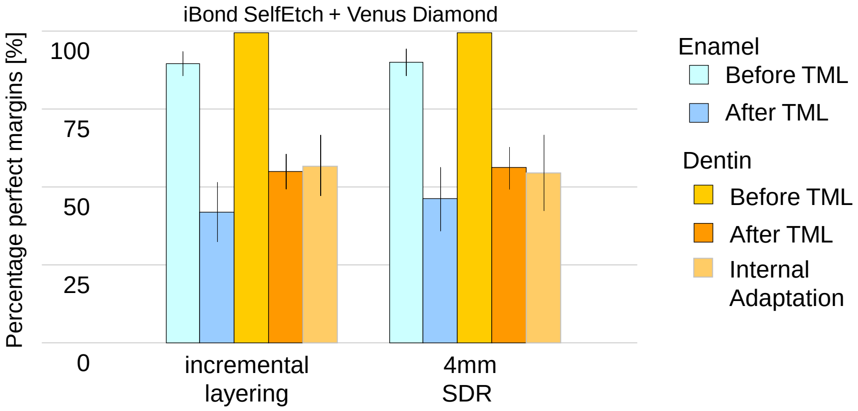

Figure 30 Percentage of perfect margins and internal adaptation before and after thermomechanical loading comparing incremental layering technique to SDR iBond SelfEtch + Venus Diamond

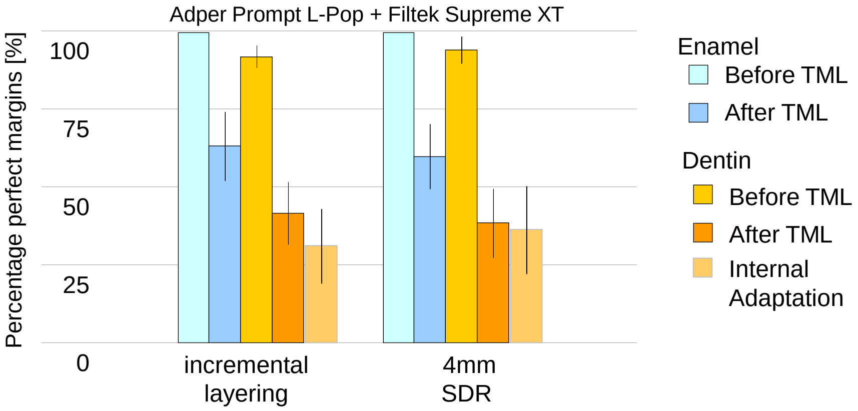

Figure 31 Percentage of perfect margins and internal adaptation before and after thermomechanical loading comparing incremental layering technique to SDR Adper Prompt L-Pop + Filtek Supreme XT

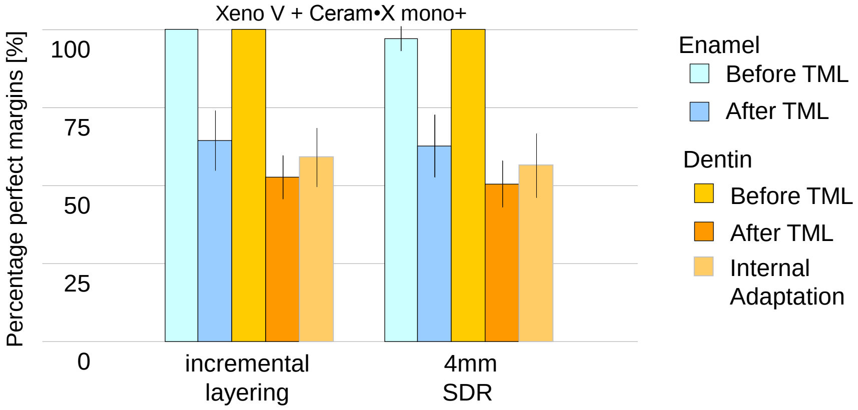

Figure 32 Percentage of perfect margins and internal adaptation before and after thermomechanical loading comparing incremental layering technique to SDR Xeno V + Ceram•X mono+

4.3.5 Class II Restorations; Microleakage

The purpose of this study was to evaluate the microleakage of Class II cavities restored with SDR™ material and Esthet•X® HD composite. Another flowable/universal composite material restored by two different procedures was also included in the study.

Samples were prepared as described in Section 4.3.3 (Marginal Integrity). The restored teeth were coated with 2 layers of nail varnish applied up to within 1 mm of the bonded interfaces. In order to avoid desiccation effects, the teeth were immersed in distilled water for 20 minutes prior to immersion in the tracer solution for 24 hours. Ammoniacal silver nitrate was prepared according to the protocol previously described (Tay, FR et al, 2002). Tooth slabs were placed in the tracer solution in total darkness for 24 hours, rinsed thoroughly with distilled water, and immersed in photo-developing solution for 8 hours under a fluorescent light to reduce silver ions into metallic silver grains within gaps along the interface.

The teeth were subsequently rinsed under running water to remove external dye. The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into two parts. The dye penetration was then recorded (in mm) for each slab and a mean value was obtained for each tooth. Dye infiltration was expressed as a percentage of the total area of the cavity. Microleakage values were statistically analyzed by Two-way ANOVA and Tukey test at the 5% confidence level. The results are presented in Figure 33.

As noted in the marginal integrity section, the results of this evaluation again confirm that the bulk (4 mm) placement of SDR™ material in combination with Esthet•X® HD composite performs statistically equivalently to that of the traditional, incrementally placed, 1 mm of flowable with universal composite. Again, the experimental group also confirms that bulk placement of a traditional flowable material leads to statistically poorer results, presumably due to higher shrinkage and polymerization stress.

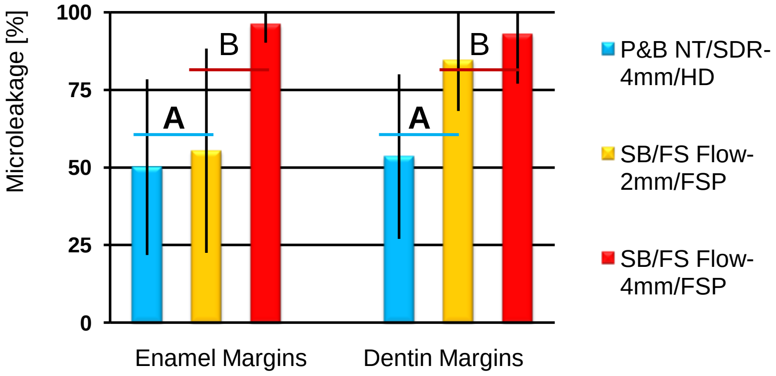

Figure 33 Microleakage of restored Class II cavities using SDR™ material and other systems

4.3.6 Class II Restorations; Internal Cavity Adaptation

The purpose of this study was to evaluate the internal adaptation of Class II cavities restored with SDR™ material and Esthet•X® HD composite. Another flowable/universal composite material restored by two different procedures was also included in the study.

Samples were prepared as described in Section 4.3.3 (Marginal Integrity). The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). One section of each tooth was selected for gap formation analysis using a replica technique. Slabs were embedded in epoxy resin and finished with 400, 600, 1200, and 2400-grit SiC paper under water and then polished with 6, 3, 1, and 0.25 micron diamond paste using a polishing cloth. An impression of the specimens was taken using a VPS impression material

(Aquasil Ultra XLV Smart Wetting® Impression Material) and replicas were made with epoxy resin (Epoxycure, Buelher). Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of interfacial gaps was determined (in mm) using an image analysis software (Image J, NIH). Results were statistically analyzed by ANOVA and Tukey Tests. The results are presented in Figure 34.

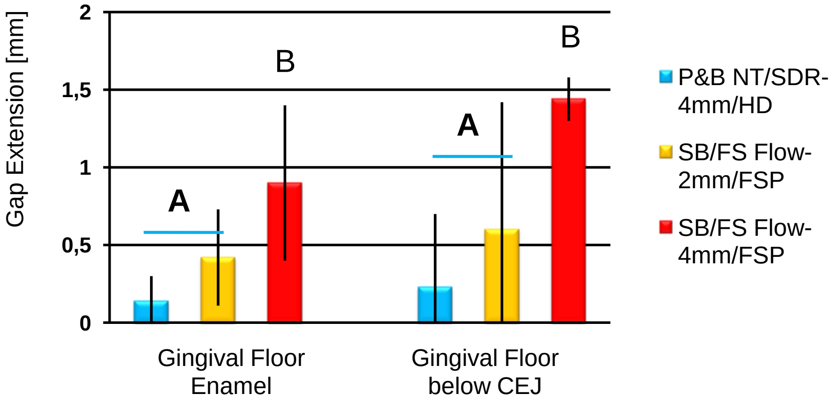

Figure 34 Internal Cavity Adaptation of restored Class II cavities using SDR™ material and other systems

As noted in the marginal integrity and microleakage sections, the results of this evaluation of internal adaptation again confirm that the bulk (4 mm) placement of SDR™ material in combination with Esthet•X® HD composite performs statistically equivalently to that of the traditional, incrementally placed, 1 mm of flowable with universal composite. This feature is critically important to ensure that the entire internal aspects of the cavity have been sufficiently coated with the flowable material. Again, the experimental group also confirms that bulk placement of a traditional flowable material leads to statistically poorer results, presumably due to higher shrinkage and polymerization stress.

5 Other Mechanical, Physical & Miscellaneous Properties

The following sections describe additional mechanical, physical and miscellaneous properties of SDR™ material. As will be noted from the extensive list of properties that follow, the SDR™ material product often demonstrates the most advantageous qualities in each set of test results. Descriptions of tests methods are included in the Appendices. Where applicable, standardized test procedures following ISO international standards were employed.

5.1 Compressive Strength & Modulus of Elasticity

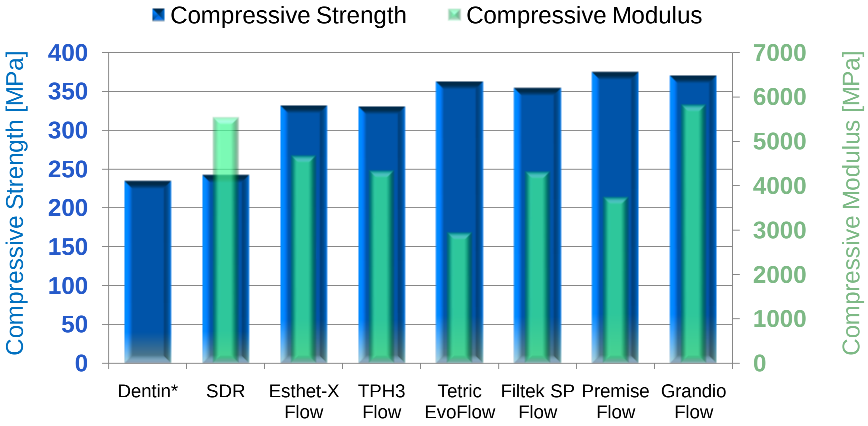

Figure 35 Compressive strength & modulus of SDR™ material & other flowable composites
* Anusavice, K., Science of Dental Materials, 10th Edition, 1996

5.2 Flexural Strength & Modulus of Elasticity

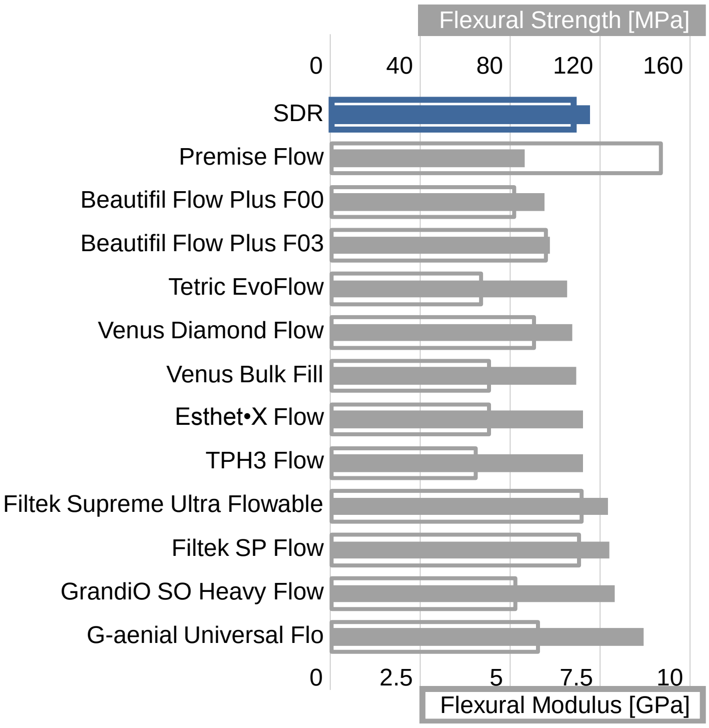

Figure 36 Flexural strength & modulus of SDR™ material & other flowable composites measured after 24 hours

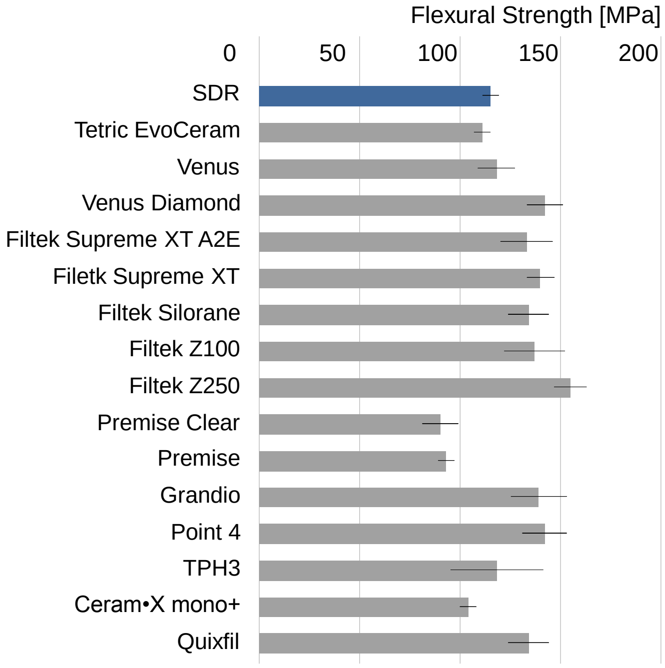

Figure 37 Flexural strength of SDR™ material & other composites measured after 24 hours
(Shade A2 or Universal if not specified differently)

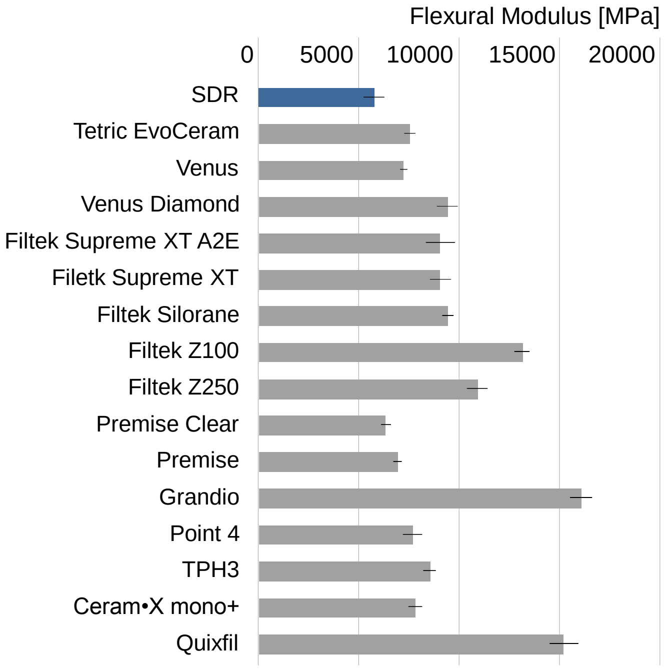

Figure 38 Flexural modulus of SDR™ material & other composites measured after 24 hours
(Shade A2 or Universal if not specified differently)

5.3 Fracture Toughness

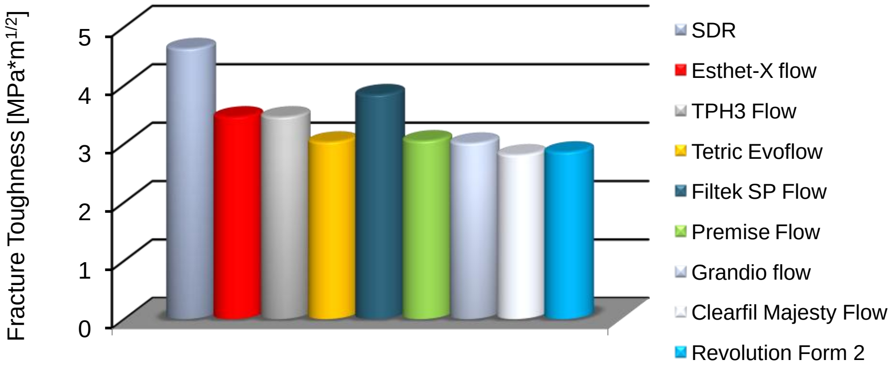

Figure 39 Fracture toughness of SDR$^{™}$ material and other flowable composites

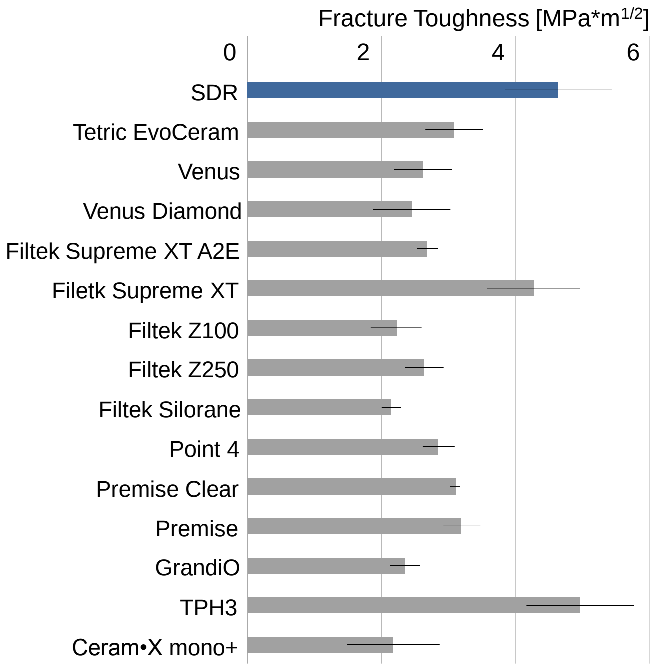

Figure 40 Fracture toughness of SDR™ material and other composites (Shade A2 or Universal if not specified differently)

Fracture toughness is a measurement to assess the resistance to crack propagation within a restorative material when placed under occlusal loading. Resistance to fracture and cracking in gingival and proximal margins is an important aspect of the SDR™ material. As can be noted from Figure 39, SDR™ material has the highest toughness among the flowable materials tested.

5.4 Diametral Tensile Strength

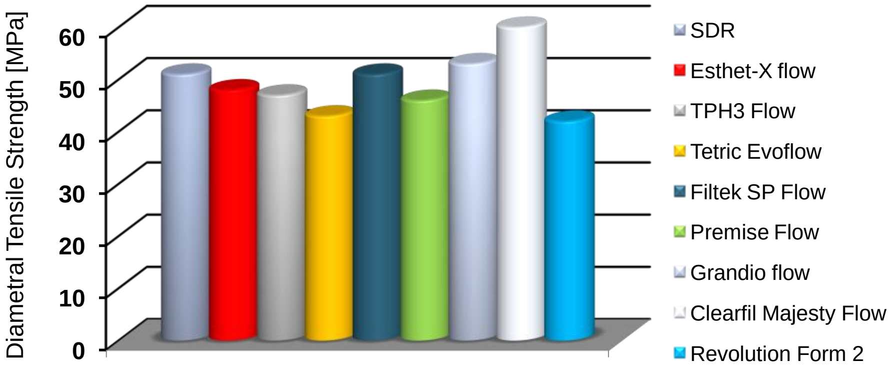

Figure 41 Diametral strength of SDR™ material & other flowable composites

Another measure of resistance to fracture is the diametral tensile strength of a material. In this test, a compressive load is placed on the flat side of a short cylindrical disk. The application of this compressive force results in tensile stress within the specimen that passes through the center of the disk. The resulting tensile stress is directly proportional to the applied compressive load applied. The testing procedure approximates forces that can be placed on composites under chewing forces observed in the mouth, measuring the resistance of the material to fractures.

5.5 Radiopacity

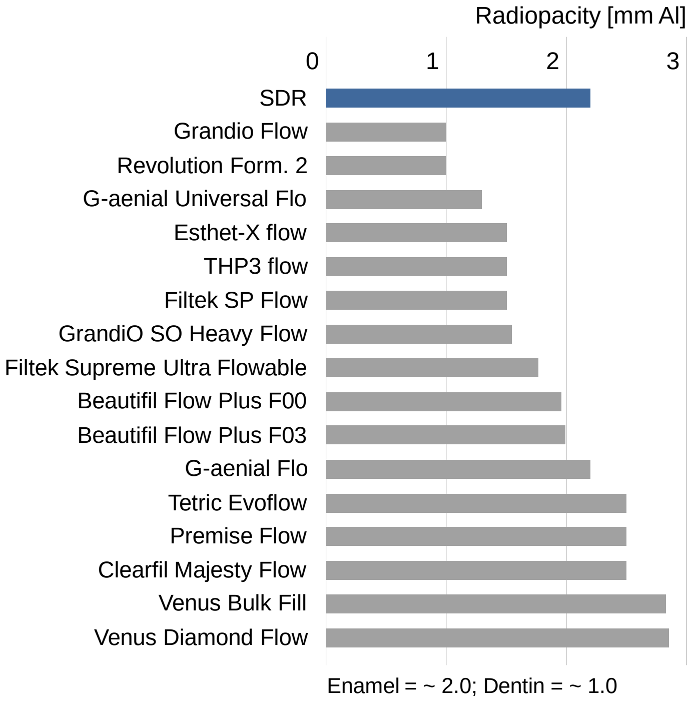

Figure 42 The radiopacity of flowables was measured and compared to the approximate radiopacity of dentin and enamel

ADA Professional Product Review, Vol. 4, Issue 2, Spring 2009 states that flowables should have radiopacity ≥ to enamel, including bases. As noted from the slide, SDR™ material meets this recommendation, while several other materials have reduced or marginal radiopacity.

5.6 Water Solubility & Water Sorption

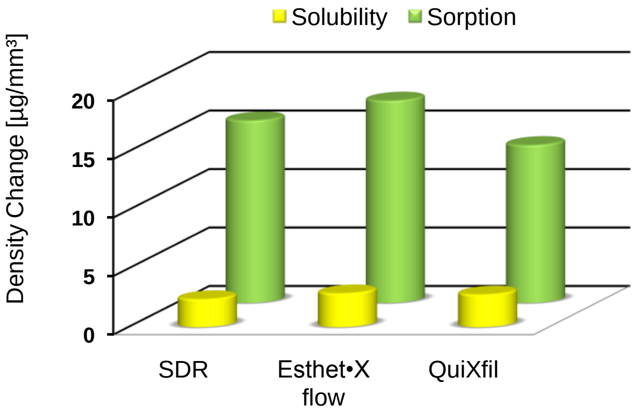

Figure 43 Water solubility and water sorption using ISO standard test methods

Water solubility and water sorption play an important role in the lifespan of composite restoratives. Limits for a materials water solubility and sorption have been established in the International Standard Organization (ISO) standard for polymer based restorative materials to be 7.5 µg/mm^3 and 40 µg/mm^3, respectively. SDR™ material falls within these parameters, having solubility and sorption values similar to Esthet•X® flow and QuiXfil® Posterior Restorative.

5.7 Compatibility with Universal Composites

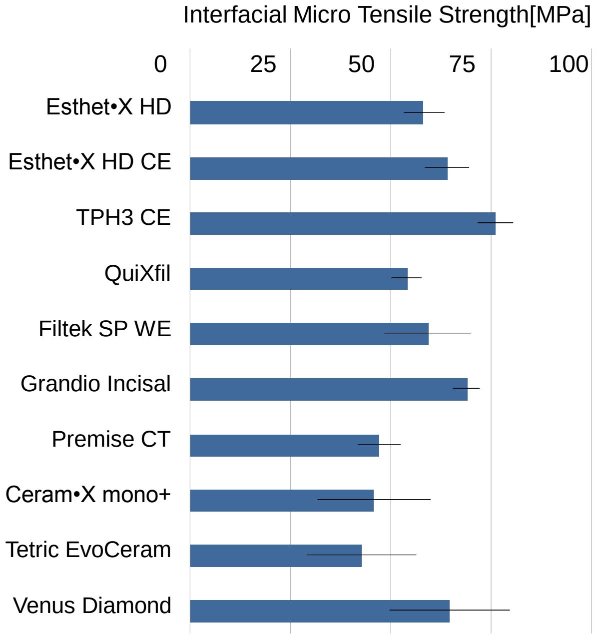

Figure 44 Compatibility of SDR™ material with various Universal / Posterior Composites (Shade A2 or Universal if not otherwise specified.)

As noted in the previous sections, the chemistry of SDR™ material comprises traditional methacrylate functionality within the novel SDR™ resin technology. This enables the SDR™ material to react effectively with traditional methacrylate based adhesives and other composite restorative materials. When using the SDR™ material as a base or liner in a composite restoration, the ability to bond to the overlaying restorative is obviously a critical requirement. In the test results on micro tensile bond strength of layered samples shown above, the bond between SDR™ material and numerous universal composite restorative materials was evaluated. As expected, there is a strong chemical bond between the SDR™ material and all of the methacrylate based universal/posterior composite restorative materials.

5.8 Compatibility with Adhesives

In order to evaluate whether SDR adheres to a specific adhesive after application on dentin SBS (Shear Bond Strength) was measured using the system composite (composite of the same manufacturer as for the adhesive) in one group and SDR in the other.

Figure 45 exemplarily shows the mean SBS of one adhesive when either the system composite or SDR was bonded to dentin. Furthermore, the 95% confidence interval is shown as well.

Finally the overlap between both confidence intervals is marked clearly showing that SDR provides equal SBS compared to the system composite of the respective adhesive. The overlap also describes the array of bond strength covered in this test.

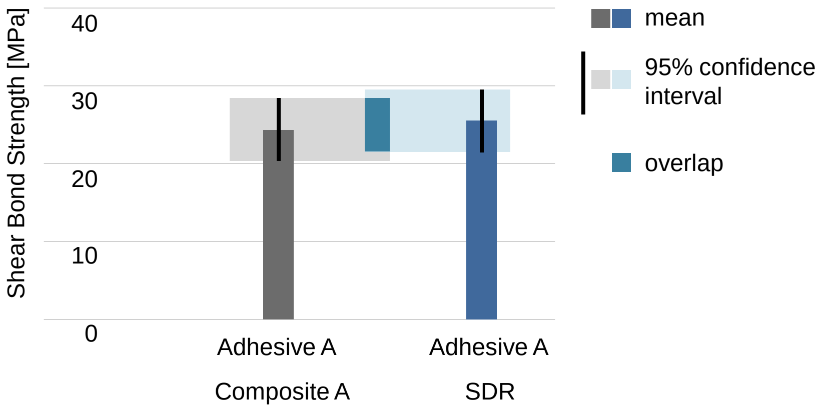

Figure 45 Mean SBS and overlapping confidence interval

Figure 46 shows this overlap of confidence intervals for 6 composite/adhesive combinations tested against SDR using the respective adhesive.

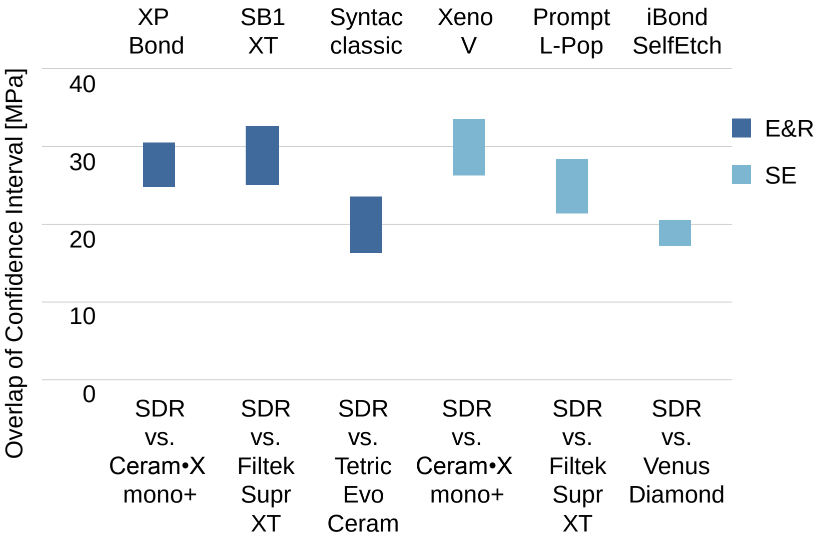

Figure 46 Compatibility of SDR with Etch&Rinse (E&R) and Self-Etch (SE) adhesives

From Figure 46 it can be concluded that there was no difference in SBS whether the system composite or SDR was bonded to dentin.

5.9 Color Stability

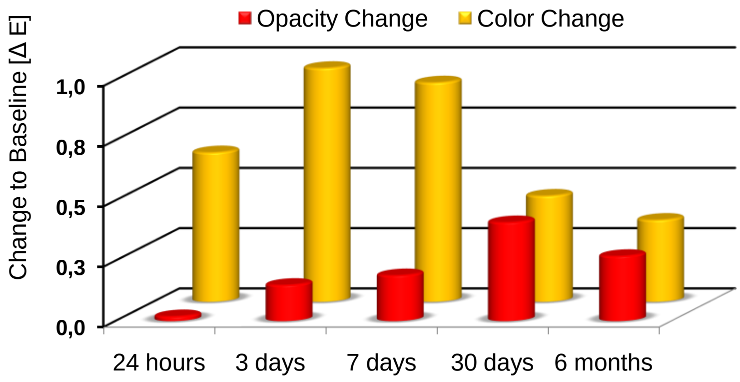

Figure 47 The color stability of SDR™ material after water storage. (Note: After exposure to UV Irradiation no noticeable color change was observed)

The color stability of SDR™ material was evaluated following the procedures outlined in the applicable ISO standards for color stability of restorative materials. As recorded above, the color stability of SDR™ material is excellent and well below the delta E value of 2.0, the point at which only those with very sharp visual acuity can begin to observe a change in shade. No noticeable color change was observed with SDR™ material after excessive UV irradiation (See Apendix Color Stability for details of the testing protocol).

5.10 Fluoride Release

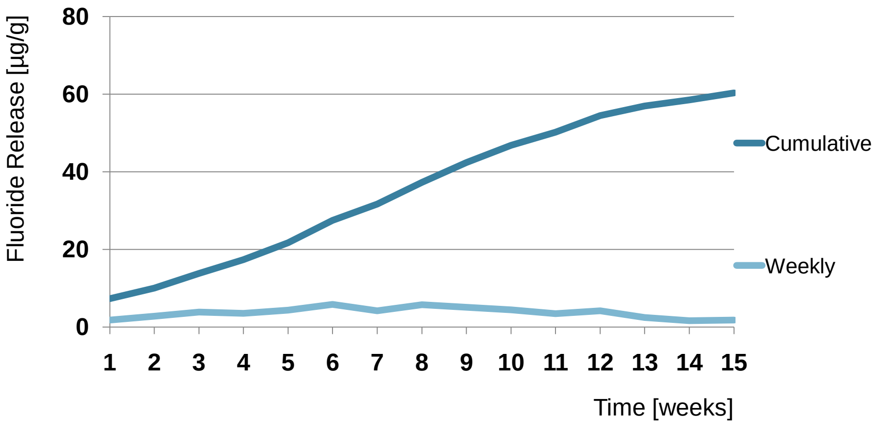

Figure 48 The Fluoride release of SDR™ material after storage in deionized water

Fluoride release from specimens of SDR™ material immersed in deionized water was measured and recorded weekly. A measurable release of Fluoride was recorded for each observation, with the release levels reaching a steady state after 15 weeks.

5.11 Overview Material Properties

SDR - Other technical data	**Value**	**Unit**
Fracture toughness	4.63	MPa*m$^{1/2}$
Flexural modulus	5753	MPa
Compressive strength	242	MPa
Compressive modulus	5539	MPa
Diametral tensile strength	50.7	MPa
Volume shrinkage	3.5	%
Water sorption	15.6	µg/mm^3
Water solubility	2.4	µg/mm^3
Depth of cure	4.1	mm
Radiopacity	2.2	mm Al
Working time	90	sec
Filler content (weight / volume)	68 / 45	%
Filler size (average)	4.2	µm

Table 3 Overview Material Properties SDR

6 Clinical Studies

Principle Investigators:

Dr. John Burgess

Dr. Carlos Muñoz

Overview of Study Methods:

Subjects in need of Class I and/or Class II restorations were enrolled into the clinical trials. Respective university standards were applied to isolation, anesthesia, caries removal and basic cavity design. All cavity preparations were etched for 15 seconds with 37% phosphoric acid, then rinsed and dried but not desiccated. Prime & Bond® Bonding Agent (DENTSPLY Caulk, Milford, DE) was applied to all dentin and enamel surfaces and light cured for 10 seconds. SDR™ (DENTSPLY Caulk, Milford, DE) was then applied in increments up to 4 mm as needed to fill the cavity up to the dento-enamel junction (see Figure 49). An experimental low stress micro-hybrid composite resin (DENTSPLY Caulk, Milford, DE) or Esthet•X® HD composite (DENTSPLY Caulk, Milford, DE) was then layered onto the base to complete the anatomic form of the restoration. Restorations were finished and polished using the Enhance® Finishing System and the PoGo® One Step Diamond Micro-Polisher (DENTSPLY Caulk, Milford, DE).

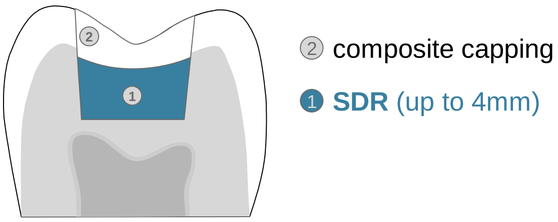

Figure 49 Schematic illustration of filling technique using SDR and a capping material.

Subjects were recalled for evaluation approximately six, twelve and twenty four months following placement of their restoration(s). The clinical parameters relevant to the base material evaluated at Baseline (within one week of placing restorations) and at the six month recall were as follows:

- Fracture – records whether a restoration has fractured and if so whether localized or in bulk. Theoretically, bulk fracture could result from a deficiency in the base material.
- Proximal Contact – evaluates the degree of contact obtained with adjacent teeth in the case of Class II restorations. In some situations the contact area of the restoration might consist of base material, either wholly or in part.
- Recurrent Caries – records whether there are recurrent caries associated with the restoration. This parameter is relevant for Class II restorations since the base material is exposed along certain margins of the restoration where recurrent caries may develop.
- Sensitivity – evaluates the presence or absence and severity of post operative sensitivity and may be relevant to the base material.
- Gingival Index – a measure of the inflammatory state of the gingiva adjacent to the restoration. This parameter is relevant only to the base material in Class II restorations.

For details of the clinical scoring criteria see section 6.1.

Results for Restorations SDR™ material:

Number of Subjects/Restorations

	Total
Baseline	87/170
6 Months	81/156
12 Months	69/131
24 Months	63/123

Eighty-seven subjects were enrolled into this clinical trial, receiving a total of 170 Class I and Class II restorations. All restorations were evaluated at the Baseline examination within seven days of the operative procedure. After 24 months, 123 restorations in 63 subjects were available for evaluation representing a recall rate of 72% for both subjects and restorations.

Fracture/Surface Defects

		TOTAL
Baseline (%)	A	167 (98)
	B	3 (2)
	C	
6 Months (%)	A	145 (93)
	B	9 (6)
	C	2 (1)
12 Months (%)	A	124 (94)
	B	6 (5)
	C	1 (1)
24 Months (%)	A	116 (94)
	B	6 (5)
	C	1 (1)

Defect free restorations constituted 98%, 93%, 94% and 94% of the Baseline 6 month, 12 month and 24 month recall evaluations respectively. The “B” rating indicates a small, repairable fracture or void confined to the occlusal surface. Repairs in this category often require recountouring the restoration. Throughout this trial a total of eight restorations were given this rating. The “C” rating reflects a more extensive defect compared with a “B” rating and requires that the restoration be repaired or replaced. During this trial a total of four restorations received the “C” rating, one of which required replacement. All restoration defects occurred within the capping agent and were not considered related to the base material.

Proximal Contact

		TOTAL
Baseline (%)	A	104 (91)
	B	9 (8)
	C	1 (1)
6 Months (%)	A	100 (89)
	B	11 (10)
	C	1 (1)
12 Months (%)	A	85 (92)
	B	6 (7)
	C	1 (1)
24 Months (%)	A	69 (89)
	B	5 (6)
	C	4 (5)

For the four evaluation intervals interproximal surfaces received “A” ratings of 91%, 89%, 92% and 89% respectively. An “A” rating indicates the optimal level of contact. Clinicians were able to achieve contact in Class II restorations quite readily using the appropriate matrix techniques and contact was by and large maintained throughout the trial. A few restorations decreased in scores while some increased. In addition to the clinical evaluation, Class II study models of approximately two-thirds of the Class II restorations were observed for broadening of contacts per past ADA guidelines for posterior composite resins. Broadening of contacts would indicate interproximal wear was occurring even if not reflected in clinical scores. No such broadening of interproximal contacts was observed on study models at any recall interval.

Recurrent Caries

		TOTAL
Baseline (%)	A	170 (100)
	C	
6 Months (%)	A	156 (100)
	C	
12 Months (%)	A	130 (>99)
	C	1 (<1)
24 Months (%)	A	123 (100)
	C	

Recurrent caries was associated with one restoration on the occlusal surface adjacent to the capping agent which was in need of repair. There were no observations of recurrent caries associated with the base material.

Sensitivity – Categorical Method

Baseline (%)	A	50 (100)
	B	
	C	
	D	
6 Months (%)	A	45(100)
	B	
	C	
	D	
12 Months (%)	A	35 (100)
	B	
	C	
	D	
24 Months (%)	A	29 (91)
	B	3 (9)
	C	
	D	

Sensitivity - VAS

	Mean VAS Score
Baseline	1.85
6 Months	1.15
12 Months	1.49
24 Months	1.42

Sensitivity was scored differently at the two study sites due to differing levels of experience with evaluation methods. At one site, subjects were interviewed in order to record the level of sensitivity they were experiencing at Baseline (5-7 days following treatment) and after 6, 12 and 24 months. Mild sensitivity was associated with 3 restorations but not until the 24 month recall evaluation. Given the low severity and the delayed time of onset, a causal relationship for these three restorations with the base material was considered unlikely.

At the other site, a cold stimulus was applied to the tooth and subjects were asked to record their level of sensitivity by placing a mark on a 10 cm line. The line was anchored at one end with a 0, indicating no sensitivity and at the other with a 10, indicating the worst pain imaginable. The length of the interval between 0 and 10 was measured and recorded as the VAS score. Sensitivity was evaluated 5-7 days following treatment and at each recall evaluation. Scores of zero sensitivity are rare in a vital tooth since a cold stimulus is being applied. The mean scores recorded at all evaluation intervals are very low. In a study by Browning (Operative Dentistry, 2007, 32-2, 112), mean VAS scores of 2.1 were recorded following application of a cold stimulus in teeth prior to treatment with Class I or II restorations, presumably a normal response. The sensitivity evaluations at both sites are indicative of no post-operative sensitivity.

Gingival Index

	Mean Gingival Index
Baseline	0.24
6 Months	0.26
12 Months	0.30
24 Months	0.35

Gingival scores reflected no inflammation to mild inflammation of the gingival tissue in contact with the base material both at Baseline (before treatment) and all recall intervals. Since mild gingival inflammation, a score of 1, is common with or without a restoration in place, these scores indicate an acceptable state of health and showed little change on recall examinations. The base material therefore had no adverse effects on the gingival tissue.

Retention

		TOTAL
Baseline (%)	A	170 (100)
	C	
6 Months (%)	A	156 (100)
	C	
12 Months (%)	A	131 (100)
	C	
24 Months	A	122 (>99)
	C	1 (<1)

One restoration that had a fracture within the capping agent in the marginal ridge area was scored “C” indicating a partial loss of the restoration.

Conclusions:

Based upon the parameters evaluated in these trials, the results presented in this report support the conclusion that the low stress resin when used as a bulk fill base in Class I and II restorations with a conventional universal composite resin as an occlusal capping agent exhibited acceptable performance with respect to safety and efficacy after two years. Several restorations showed minor surface defects. Three fractures within the capping agent required repair and one restoration was replaced. There was essentially no post-operative sensitivity related to the use of the low stress resin, and the response of the gingiva in contact with the material was within normal limits. There were no observations of recurrent caries associated with the low stress resin and there were no reports of adverse events

6.1 CLINICAL SCORING CRITERIA

Fracture	
A =	None
B =	Localized – clinically acceptable with minor repair
C =	Bulk – replacement or major repair required

Proximal Contact **(Baseline assessment only)**	
A =	Dental floss “snaps” through contact
B =	Dental floss meets resistance but doesn’t “snap” – acceptable contact
C =	Dental floss meets little to no resistance

Recurrent Caries	
A =	No caries present
C =	Caries present and associated with the restoration

Retention	
A =	Completely retained
C =	Partially retained

Sensitivity **VAS using cold stimulus** **Interview – for sensitivity to other stimuli, use scale below**	
A =	No sensitivity
B =	Mild sensitivity to thermal or pressure stimuli
C =	Significant complaint or spontaneous response
D =	Severe sensitivity, intervention required

Gingival Index	
0 =	Normal gingival
1 =	Mild inflammation, slight change in color, slight edema, no bleeding on probing
2 =	Moderate inflammation, redness; edema and glazing; bleeding on palpation
3 =	Severe inflammation, marked redness and edema, ulceration, tendency to spontaneous bleeding

7 Summary

In summary, SDR™ material has very low polymerization shrinkage coupled with exceptionally low polymerization stress. In addition, SDR™ material possesses a high depth of cure and degree of conversion that optimizes physical and mechanical properties. As a result of these exceptional properties, SDR™ material is the 1st flowable composite base suitable for bulk (4 mm) placement in Class I and II cavities, which can result in time savings of up to 30% over traditional restorations. As demonstrated in this manual, the chemistry of SDR™ material, while unique in its polymerization mechanism, remains compatible with all methacrylate based chemistries, including total or self-etch adhesives and universal composites restoratives. The optimized handling and self-leveling consistency of the SDR™ material is ideal cavity adaptation, especially in posterior restorations. Finally, the universal shade of SDR™ material enables simplified placement options.

8 Appendices: Additional Information

For comparative measurements of various parameters the following materials were used:

Flowable Composite	**Manufacturer**
Beautifil Flow Plus F00	Shofu
Beautifil Flow Plus F03	Shofu
Clearfil Majesty™ Flow	Kuraray
Esthet•X® flow	DENTSPLY
Filtek Supreme Ultra Flowable	3M Espe
Filtek™ Supreme Plus Flowable	3M Espe
G-aenial Flo	GC
G-aenial Universal Flo	GC
Grandio Flow	VOCO
GrandiO SO Heavy Flow	VOCO
Premise™ Flowable	Kerr
Revolution™ Formula 2	Kerr
Tetric® EvoFlow	Ivoclar Vivadent
TPH®3 Flow	DENTSPLY
Venus Bulk Fill	Heraeus Kulzer
Venus Diamond Flow	Heraeus Kulzer

Composite	**Manufacturer**
Ceram•X mono+	DENTSPLY
Estelite Sigma Quick	Tokuyama
Esthet•X	DENTSPLY
Filtek Silorane	3M Espe
Filtek Supreme Plus (A2B)	3M Espe
Filtek Supreme Plus (A2E)	3M Espe
Filtek Z100	3M Espe
Filtek Z250	3M Espe
Gradia Direct Anterior	GC
GrandiO	VOCO
Herculite XRV	Kerr
Point 4	Kerr
Premise (Body)	Kerr
Premise (Clear)	Kerr
Quixfil	DENTSPLY
Tetric EvoCeram	Ivoclar Vivadent
TPH3	DENTSPLY
Venus	Heraeus Kulzer
Venus Diamond	Heraeus Kulzer

8.1 Appendix A: Instructions for Use

The up-to-date version can be found in all European languages on www.dentsply.eu.

8.2 Appendix B: Polymerization Shrinkage & Stress

8.2.1 Volume Shrinkage

Composite specimens were prepared by curing the composite in a stainless steel mold, 2.5 mm thick x 10 mm in diameter, with Triad 2000 for 2 minutes each side. The densities of uncured and 24 hour post-cured restorative materials were determined using a Helium Pycnometer (MicroMeritics AccuPycII 1340). The volume shrinkage was calculated as:

$$Volume\ Shrinkage = \frac{\text{Density Cured - Density Uncured}}{Density\ Cured \times 100}$$

8.2.2 Polymerization Stress: NIST Tensometer

NIST Tensometer (Eichmiller FC, 2004; Lu H et al, 2004) was used to determine polymerization stress. The polished quartz glass rods were silanated by 2 layers of 2% A-174 silane/acetone solution. Uncured restorative material was injected into a cell between 2 glass rods, 6 mm diameter x 2.25 mm deep. The composite was cured with a Spectrum 800 halogen light at a light intensity of 300-400 mW/cm^2 for 60 seconds. The stress was recorded 60 minutes post-cure.

8.2.3 Polymerization Stress: Photoelastic Stress Measurement

Prof. C.P. Ernst, Mainz, Gemany

Conventional PMMA acrylic materials using a photoelastic constant of f_σ = 230 N/mm have been used in a photoelastic investigation of visible light curing. Specially designed photoelastic materials with a lower photoelastic constant (f_σ = 10.5 N/mm), such as Araldit B (Tiedemann & Betz GmbH, Garmisch-Partenkirchen, Germany), allow the determination of isochromatic rings, visualizing the strain in the material. From this measured strain, stress values [MPa] can be calculated. The inner surfaces of preparations (diameter 4.0 mm, 4 mm depth) in Araldit B resin plates (40 x 40 x 4 mm) were pre-treated with a silicating system (Rocatec, ESPE-Sil, Visio-Bond, 3M ESPE, Germany) to ensure bonding of the resin composite to the plates.

Ten specimens of each material were polymerized using the standard exposure mode (60 s, 500 mW/cm^2) of a quartz-tungsten-halogen-based dental curing light (Translux Energy, Heraeus-Kulzer, Germany). (Figure 50)

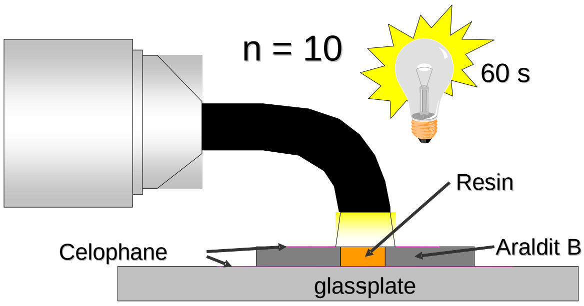

Figure 50 Curing of the samples

Photoelastic images were recorded 4 min and 24 h post-curing in a photoelastic workstation that allowed exact placement and filter (Linos Photonics GmbH, Göttingen, Germany) angulations to obtain constant light and dark fields in the examination with a stereo-microscope (Steri 2000, Zeiss, Göttingen, Germany). A cold light source from underneath the filters allowed the illumination of samples. A digital camera (color compact camera Teli CS-5260 DP, 752x582 pxls) was used to transform the images into a computer with a software suitable to identify the isochromatic ring diameters (Matrox Inspector, Rauscher GmbH, Olching, Germany). (Figure 51)

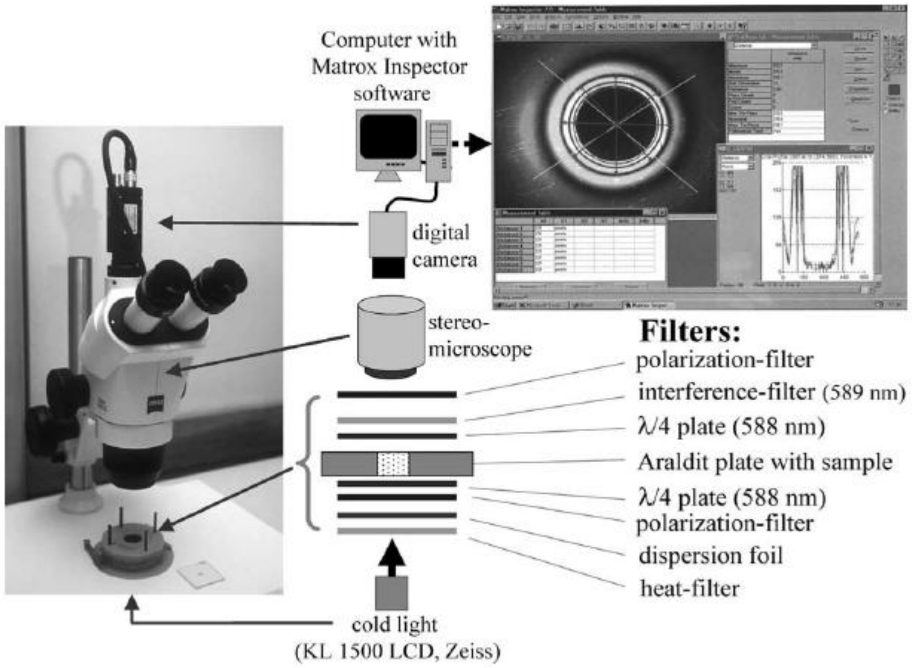

Figure 51 Set-up to measure isochromatic rings after polymerisation

Photoelastic stress investigations are based on certain fundamental physical principles. The main photoelastic equation is

$$\delta = (\sigma_1 - \sigma_2)\ C\ d/\lambda$$

where:

- δ is the material strain
- C is a material constant [10^{-6} mm s^2/kg]
- λ is the wavelength of the light [nm]
- d is the thickness of the specimen [mm]
- $\sigma_1 - \sigma_2$ the main strain-difference

The material constant C, as well as the wavelength λ can be combined into a common photoelastic constant f_σ ($f_\sigma = \lambda/C$) which is 10.5 N/mm for the Araldit B-material used in this study. By placing this constant into the first equation the result is:

$$\delta = (\sigma_1 - \sigma_2)\ d/\ f_\sigma$$

To obtain polymerization stress values (σ_0) from the isochromatic-diameters, the equation has to be reformulated:

$$\sigma_0 = \delta_x \frac{D^2_x}{D^2_i} \frac{f_\sigma}{2d}$$

where:

- δ_x is the order of the isochromatic ring
- D^2_x the diameter of the isochromatic ring [mm]
- D^2_i is the diameter of the resin filling (specimen) [mm]
- f_σ is the photoelastic constant [N/mm]
- d is the thickness of the Araldit platelets [mm].

Because the terms f_σ (=10.5 N/mm), d (= 4.0 mm), and D_i (= 4 mm) remain constant, they can be combined in a common constant "*k*", allowing use of an even simpler equation

$$\sigma_0 = k\, \delta_x\, D^2_x$$

Polymerization stress data (MPa) were calculated on the basis of the localization and diameter of the first order isochromatic curves, obtained from the Araldit plates (Figure 52).

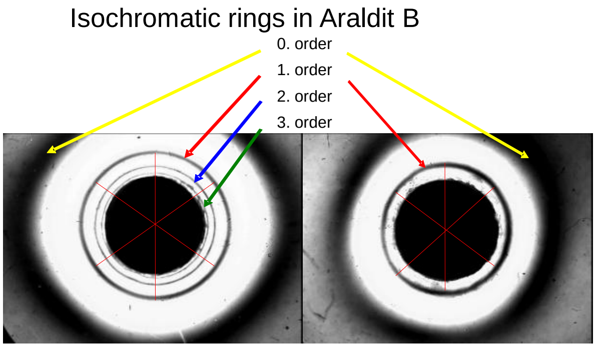

Figure 52 Visualization of the isochromatic rings found in a photoelastic investigation on photo-curable resin composites.
The isochromatic ring of first order was chosen for all materials investigated

From an isochromatic ring of zero order, only the inner part of the ring is visible. The first order isochromatic ring (number of isochromatic order rises from outside to inside) is the first completely visible ring in a photoelastic image. The higher the isochromatic ring order number, the closer it is to the restoration. While the strain difference between the first and second isochromatic rings is almost 100 %, the difference will become smaller the higher the order number of the ring. For example, the difference between a ring of 9th and 10th order will only be 10 %. To obtain comparable results with low standard deviations, an isochromatic ring of a lower order should be chosen. Due to the fact that the first order isochromatic ring is thicker than higher order rings, it is more difficult to measure its diameter exactly. The second order isochromatic ring is thinner and therefore easier to detect than that of the first order. But isochromatic rings of second order were not seen in some of the low shrinkage materials. Therefore, to obtain compatibility, the first order isochromatic rings were chosen for all samples to determine polymerization shrinkage data. Additionally, higher isochromatic ring orders than two were not seen in each material investigated.

8.2.4 Polymerization Stress: Stress-Strain-Analyzer

Dr. N. Ilie, Munich, Germany

Five commercially available and two experimental composite materials were analyzed in this study by measuring their shrinkage behaviour during polymerization as well as the mechanical properties. The polymerization stress and the time until gelation of the tested material was investigated with a Stress-Strain-Analyzer (SSA T80, Engineering Consultancy Peter Dullin Jr., Munich) which continuously measured the contraction force generated by polymerizing the restorative material with the light exposure mentioned above, with compensation of the compliance of the machine. The composite specimens were placed between two aluminium attachments with a distance of 4 mm and a height of 2 mm. One attachment was connected to a load sensor and the other to a Piezo-actuator. A PTFE coated plastic tray was fixed on the testing machine, exactly fitting the two attachments, building a simulated cavity between the attachments (C-factor: 0.3). The functional surfaces of the two attachments were cleaned and coated with ROCATEC-Pre, -Plus (ESPE), followed by further application of a silane-coupling agent (ESPE-Sil, ESPE). The tested composite was then applied in one 2 mm increment. The contraction force generated by polymerizing the composite was continuously measured and recorded for 300 s after photo-initiation. Each experiment was conducted at room temperature and repeated ten times for each material. Maximum contraction stress during the recorded time and time ($t_{0.5N}$) needed to exceed a force threshold of 0.5 N (arbitrarily defined as the time until gelation) were compared.

8.3 Appendix C: Curing Effectiveness Methods

8.3.1 Depth of Cure Based on ISO 4049:2009(E)

The restorative material was light cured for 20 seconds in a stainless steel mold with a cylindrical chamber, 4 mm in diameter and 8 mm long (10 mm long for SDR™) and a Whatman No. 1 filter paper as background with a Spectrum 800 halogen light at a light intensity of 500-550 mW/cm^2. The uncured side was scraped away using a plastic spatula and the thickness of the remaining, cured composite was measured by a micrometer. The depth of cure was the remaining thickness divided by two.

8.3.2 Degree of Conversion: NIR Method

The restorative material was filled in a stainless steel mold with a cylindrical chamber, 13 mm in diameter and various depths (2 mm, 3 mm, 4 mm, and 5 mm). The mold was sandwiched between two micro slides and was placed on top of a Whatman No. 1 filter paper as background. The restorative was light cured for 20 seconds with a Spectrum 800 halogen light at a light intensity of 500-550 mW/cm2. On a Nicolet 6700 FTIR, a Smart NIR Updrift Accessory was installed. The unreacted -C=C- concentration in the composite was determined by the area under the NIR spectra peak of -C=C- overtone at 6163cm-1. The C=C conversion was calculated by

$$Conversion\% = \frac{1\text{ - Area Cured}}{Area\,Uncured} \times 100$$

The conversion for both the top and the bottom surfaces was measured at 1 hour and 24 hours post cure.

8.3.3 Degree of Conversion: FTIR Method

Dr. Andre F. Reis, Guarulhos, SP Brazil

Five composite resins were tested in the study: SDR™ material (R0999-1 U, Lot 080512 – DENTSPLY Caulk), Esthet•X flow (A2 Lot 080804 - DENTSPLY Caulk), Filtek Supreme Plus flow (A2 Lot 8GH - 3M ESPE), Filtek LS (Lot 8AP - 3M ESPE) and Tetric Evoflow (A2 Lot L36209 - Ivoclar Vivadent). Three polytetrafluorethylene split molds (2 mm deep and 3 mm diameter) were filled with composite resin, and placed one on top of the other. A mylar strip was placed in between, so depth of cure (DOC) could be measured at the top surface, at 2, 4 and 6 mm. Except for Filtek LS, which was light cured for 40 seconds as recommended by manufacturer, flowables were irradiated from the top surface for 20s using a visible light curing unit with a power output of 650 mW/cm^2 (Demetron Optilux 501C). SDR™ material was also cured with a light-emitting diode (LED) unit (Bluephase 16i Vivadent), with a power output of 1100 mW/cm^2.

Five specimens of each experimental group were prepared to obtain the degree of conversion (DC) at each depth. The absorption spectrums for polymerized composites were obtained in the form of a tablet on a Spectrum 100 FTIR spectrometer (PerkinElmer - USA) for the transmission method, operating with 64 scans at a resolution of 4 cm^{-1} within a wavelength of 4000-650 cm^{-1}. For the measurement of absorption spectrums of uncured resins, the composite was inserted in the circular metallic matrix (5 mm in diameter and 2 mm in thickness) and covered by a polyester matrix between two glass plates under a weight of 10 kg to assure the compaction of the non-polymerized resin in the matrix. The absorption spectrums of the cured resins were obtained in the same manner as described above.

The direct form of determining the polymerization DC is based on the measurement of the reduction in the intensity of the stretching band of carbon-to-carbon aliphatic double bonds (C=C) of methacrylate, at 1637 cm^{-1}, when the monomer is converted to polymer. This spectroscopic procedure depends on the presence of an absorption band that is not modified with the polymerization, and serves as a normalization standard of monomer and polymer spectrums. For example, composites that have aromatic monomers, with a band of absorption in 1608 cm^{-1} can serve as internal standards of normalization; this eliminates the necessity to consider the thickness of the sample. The value of the conversion degree (DC) will be obtained by the equation (1).

$$DC = \left(1 - \frac{C}{U}\right) \times 100_{(1)}$$

Where C and U are reasons of intensity between aliphatic and aromatic C=C absorptions, after and before the polymerization, respectively. Thus the percentage of carbonic double linking that is not reacted during the polymerization reaction is determined. The DC is determined by the subtraction of the residual percentage of aliphatic C=C from 100%.

Low shrinkage composite resin (Filtek LS), do not contain aliphatic $C{=}C$ groups, consequently, the DC cannot be calculated from Eq. (1). The mean DC of Filtek LS specimens were identified through regions of the FTIR spectra between 730 and 950 cm^{-1} which corresponded with the oxirane ring-opening regions. A common internal standard was the absorption of aromatic $C{=}C$ at 1608 cm^{-1}.

8.3.4 Knoop Hardness

The restorative material was filled in a stainless steel mold with a cylindrical chamber, 13 mm in diameter and various depths (2 mm, 3 mm, 4 mm, and 5 mm). The mold was sandwiched between two micro slides and was placed on top of a Whatman No. 1 filter paper as background. The restorative was light cured for 20 seconds with a Spectrum 800 halogen light at a light intensity of 500-550 mW/cm^2. The Knoop hardness was measured with a LECO LM700AT Microhardness Tester with 200 g test load and 5 second dwell time. The Knoop hardness for both the top and the bottom surfaces was measured at 1 hour and 24 hours post cure.

8.3.5 Barcol Hardness Method

The restorative material was filled in a stainless steel mold with a cylindrical chamber, 13 mm in diameter and various depths (2 mm, 3 mm, 4 mm, and 5 mm). The mold was sandwiched between two micro slides and was placed on top of a Whatman No. 1 filter paper as background. The restorative was light cured for 20 seconds with a Spectrum 800 halogen light at a light intensity of 500-550 mW/cm^2. The hard Barcol hardness for both the top and the bottom surfaces was measured with a Hard Barcol Impresser Tester at 1 hour and 24 hours post cure.

8.4 Appendix D: Shear Bond Strength to Dentin & Enamel Test Method

8.4.1 Enamel & Dentin Bonding; Notched-Edge (Ultradent) Shear Bond Strength (SBS) to Tooth

Freshly extracted, caries-free and un-restored human molars were used. Teeth were sectioned longitudinally through the mesial, occlusal, and distal surfaces using a water-cooled diamond grit cutting disc. The sectioned molars were mounted in a cylindrical block using cold-cure acrylics, with the buccal surface exposed. The exposed surface was then coarse ground on a model trimmer until a flat dentin or enamel surface is exposed. Prior to the bonding of specimen, tooth was wet-ground on grinding wheel under running water use 120-grit SiC sanding paper, followed by 320-grit SiC sanding paper, until the surface was even and smooth when visually inspected.

The Ultradent bonding jig with a defined bond area (diameter 2.38 mm) and height (2 mm) was used. Tooth surface was prepared (etching, rinsing, etc) according to the bonding agent's DFU. The adhesive was applied and cured per its DFU. Then Ultradent mold opening was centered over the treated substrate. Composite was carefully placed into the mold and cured with a halogen at a light intensity of 550 mW/cm^2 for 40 seconds. After curing, the mold insert was carefully removed from the bonding clamp without applying any bending and shearing force to the bonded specimen. The bonded specimen was stored in 37°C DI-water for 24 hour before SBS testing. SBS test was performed on Instron 4400 at a crosshead speed of 1 mm/min.

8.4.2 Class I Micro-tensile Bond Strength

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Freshly extracted human third molars were used in this study. Five teeth were used for each experimental group (N=5). After disinfection and removal of soft tissues a standardized Class I occlusal preparation (6 mm long X 4 mm wide X 5 mm deep) was made in each tooth using coarse diamond burs operated in a high-speed hand-piece using copious air-water spray.

Prepared teeth were randomly assigned to groups according to each restoration protocol. The adhesive material(s) were applied according to the recommended manufacturer's directions. In the experiments using SDR™ material*,* the flowable material was placed in 4 mm bulk increments and light cured for 20 seconds. An occlusal layer of approximately 1 to 1 mm of Esthet•X® HD composite was incrementally added to build the final anatomy of the teeth. In the group using Filtek Supreme Flow, a 1 mm layer was applied and light cured for 20 seconds, followed by incrementally placing 2, ~ 2 mm oblique layers of Filtek Supreme Plus and light curing for 20 seconds per increment. After placing Filtek LS Self-Etch Primer and Bond according to the manufacturer's directions, Filtek LS Posterior Composite was placed incrementally using the horizontal layering technique (increments of approximately 2 mm were used). Each increment was cured for 40 seconds.

After restorative procedures, the specimens were placed in water for 24 hours prior to testing. The restored teeth were sectioned in a bucco-lingual direction into approximately 0.8 mm thick slabs with a diamond saw under water lubrication (Isomet 1000, Buehler). Four or five slabs were obtained from each tooth. Each slab was trimmed from both sides with an extra-fine diamond bur to reduce the cross-sectional area at the interface of the pulpal wall to approximately 1 mm^2. Bonded specimens were tested in tension with a universal testing machine (EZ Test, Shimadzu) using a Ciucchi's jig at a crosshead speed of 1 mm/min. The µ-TBS values were expressed in MPa, which was calculated by dividing the peak break by the cross-sectional area of the bonded interface. Data were statistically analyzed by one-way ANOVA and Tukey test at the 5% confidence level.

8.5 Appendix E: Microleakage, Gap and Marginal Integrity

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8.5.1 Class I Cavity Preparation and Restoration

Freshly extracted human third molars were used in this study. Five teeth were used for each experimental group (N=5). After disinfection and removal of soft tissues a standardized Class I occlusal preparation (6 mm long X 4 mm wide X 5 mm deep) was made in each tooth using coarse diamond burs operated in a high-speed hand-piece using copious air-water spray. Prepared teeth were randomly assigned to groups according to each restoration protocol. The adhesive material(s) were applied according to the recommended manufacturer's directions. In the experiments using SDR™ material, the flowable material was placed in 4 mm bulk increments and light cured for 20 seconds. An occlusal layer of approximately 1 to 1 mm of Esthet•X® HD composite was incrementally added to build the final anatomy of the teeth. In the group using Filtek Supreme Flow, a 1 mm layer was applied and light cured for 20 seconds, followed by incrementally placing two, ~ 2 mm oblique layers of Filtek Supreme Plus and light curing for 20 seconds per increment. After placing Filtek LS Self-Etch Primer and Bond according to the manufacturer's directions, Filtek LS Posterior Composite was placed incrementally using the horizontal layering technique (increments of approximately 2 mm were used). Each increment was cured for 40 seconds.

8.5.2 Class I Microleakage

After the restorative procedures, teeth were placed in water for 24 hours prior to testing. Restored teeth were coated with two layers of nail varnish applied up to within 1 mm of the bonded interfaces. In order to avoid desiccation artifacts, they were immersed in distilled water for 20 min prior to immersion in the tracer solution for 24 hours. Ammoniacal silver nitrate were prepared according to the protocol previously described (Tay, et al, 2002). Tooth slabs were placed in the tracer solution in total darkness for 24 hours, rinsed thoroughly in distilled water, and immersed in photo-developing solution for 8 hours under a fluorescent light to reduce silver ions into metallic silver grains within gaps along the interface. The teeth were subsequently rinsed under running water to remove external dye. The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into three parts. The degree of dye penetration was then recorded (in mm) for each one of the slabs and a mean value was obtained for each tooth. Dye infiltration was expressed as a percentage of the total area of the cavity. Microleakage values were statistically analyzed by One-way ANOVA and Tukey test at the 5% confidence level.

8.5.3 Class I Internal Cavity Adaptation

Samples were prepared as described above. After the restorative procedures, teeth were placed in water for 24 hours prior to testing. The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into three parts. The central slab in each tooth was selected for gap formation analysis using a replica technique. Slabs were embedded in epoxy resin and then finished with 400, 600, 1000 and 2000-grit SiC paper under water and then polished with 6, 3, 1 and 0.25 µm diamond paste using a polish cloth. An impression of the specimens was taken using a PVS impression material and replicas were made with epoxy resin (Epoxycure, Buehler). Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of gaps was determined (in mm) using an image analysis software (Image J, NIH). Gap extension was expressed as a percentage of the total cavity contour. Results were statistically analyzed by ANOVA.

8.5.4 Class II Cavity Preparation and Restoration

Freshly extracted human third molars were used in this study. Five teeth were used for each experimental group (N=5). After disinfection and removal of soft tissue, a standardized Class II MOD preparation was made in each tooth using a coarse diamond bur operated in a high-speed hand-piece using copious air-water spray. The margin of the mesial proximal box was placed in dentin (1 mm apical to the CEJ) and the distal margin was placed in enamel (1 mm coronal to the CEJ). Prepared teeth were randomly assigned to groups according to each restoration protocol. The prepared teeth were mounted in a jig featuring artificial training teeth that served as adjacent teeth. A contoured matrix band was placed around the teeth for restorative procedures.

The adhesive (either Prime & Bond® *NT*™ or Scotchbond 1 XT) material was applied according to the recommended manufacturer's directions. In the experiments using Prime & Bond® *NT*™/SDR™ material, the flowable material was placed in 4 mm bulk increments and light cured for 20 seconds. An occlusal layer of approximately 1 to 2 mm of Esthet•X®HD composite was incrementally added to build the final anatomy of the teeth. In the group using Filtek Supreme Flow, after application of Scotchbond 1 XT, a 1 mm layer was of the flowable material was applied and light cured for 20 seconds, followed by incrementally placing ~ 2 mm oblique layers of Filtek Supreme Plus and light curing for 20 seconds per increment, according to the manufacturer's directions. In a third, experimental group, the adhesive application was performed per manufacturer's instructions, followed by a 4 mm bulk placement of Filtek Supreme Plus Flowable and light curing for 20 seconds. An occlusal layer of approximately 1 mm of Filtek Supreme Plus was incrementally added to build the final anatomy of the teeth, with each increment cured for 20 seconds. (Note: This final procedure is **not recommended by the manufacturer**, but was performed to evaluate bulk placement performance of a flowable material with higher shrinkage and polymerization stress.)

8.5.5 Class II Marginal Integrity

After restorative procedures, an impression of the proximal boxes of each specimen was made with a VPS material (Aquasil Ultra XLV) and replicas were made using epoxy resin (Epoxycure, Buehler) for SEM evaluations of the marginal integrity. Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of marginal defects was determined (in mm) using an image analysis software (Image J, NIH). Results were expressed as a percentage of total marginal lengths.

8.5.6 Class II Microleakage

The restored teeth were coated with 2 layers of nail varnish applied up to within 1 mm of the bonded interfaces. In order to avoid desiccation effects, the teeth were immersed in distilled water for 20 minutes prior to immersion in the tracer solution for 24 hours. Ammoniacal silver nitrate was prepared according to the protocol previously described (Tay FR et al, 2002). Tooth slabs were placed in the tracer solution in total darkness for 24 hours, rinsed thoroughly with distilled water, and immersed in photo-developing solution for 8 hours under a fluorescent light to reduce silver ions into metallic silver grains within gaps along the interface.

The teeth were subsequently rinsed under running water to remove external dye. The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). Each cavity was sectioned into two parts. The dye penetration was then recorded (in mm) for each slab and a mean value was obtained for each tooth. Dye infiltration was expressed as a percentage of the total area of the cavity. Microleakage values were statistically analyzed by Two-way ANOVA and Tukey test at the 5% confidence level.

8.5.7 Class II Internal Cavity Adaptation

The specimens were sectioned longitudinally through the center of the restorations with a diamond saw (Isomet Buehler). One section of each tooth was selected for gap formation analysis using a replica technique. Slabs were embedded in epoxy resin and finished with 400, 600, 1200, and 2400-grit SiC paper under water and then polished with 6, 3, 1, and 0.25 micron diamond paste using a polishing cloth. An impression of the specimens was taken using a VPS impression material (Aquasil Ultra XLV) and replicas were made with epoxy resin (Epoxycure, Buelher). Replicas were sputter-coated with gold (MED 010) and observed under an SEM (LEO 435 VP). Representative areas of the interfaces were photographed. The extension of interfacial gaps was determined (in mm) using an image analysis software (Image J, NIH). Results were statistically analyzed by ANOVA and Tukey Tests.

8.6 Appendix F: Other Mechanical, Physical & Miscellaneous Properties

8.6.1 Compressive Strength & Modulus

A Teflon mold for the preparation of a cylindrical specimen (7 mm long x 4 mm in diameter), was filled with restorative composite and sandwiched between two Mylar cover sheets. The composite was light cured from both sides for 20 seconds using a Spectrum 800 halogen light at a light intensity of 550 mW/cm^2. After storage in deionized water at 37°C for 24 hours, the specimens were polished to 6 mm long x

4 mm in diameter using 600 grit sand paper. The compressive strength and modulus were obtained using an Instron 4400R at crosshead speed of 5 mm/min.

8.6.2 Flexural Strength & Modulus

(Based on ISO 4049:2009(E)). Stainless steel molds with a stick-shaped chamber (25 x 2 x 2 mm) was filled with composite and covered with a Mylar sheet. The stick-shaped specimens were light cured for 3 times 20 seconds with a Spectrum 800 halogen light at a light intensity of 550 mW/cm^2. After storage in deionized water at 37°C for 24 hours, the flexural strength and modulus were obtained under a three-point loading using an Instron 4400R at a crosshead speed of 0.75 mm/min.

8.6.3 Fracture Toughness

A Teflon triangular prism mold with dimensions 6 x 6 x 6 x 12 mm was slightly overfilled with the restorative composite. Any excess material was expressed from the mold by covering the material under pressure with a Mylar sheet and a glass slide. The composite was light cured using a Spectrum 800 halogen light at a light intensity of 550 mW/cm^2 for 2 minutes. The specimen was further cured in Triad 2000 for 2 minutes. The cured specimen was removed from the mold and the flash was removed from the edges using a razor knife and then carefully sanding using 600 grit sandpaper. A preset crack initiation point, approximately 0.1 mm deep, was made midway along the bottom edge of a specimen using a razor blade. The specimens were stored in deionized water at 37°C for 24 hours. The specimens were then placed into a mounting assembly with the crack initiation aligned with the split line of the holder and secured in place by two screw-tightened clamps. The assembly was loaded in tensile mode on Instron 4400R at a crosshead speed of 0.1 mm/min.

8.6.4 Diametral Strength

Cylindrical shaped mold with dimensions of 6 mm in diameter and 3 mm in height was filled with restorative composite and sandwiched between two Mylar cover sheets. The composites were light cured from both sides for 20 seconds with a Spectrum 800 halogen light at a light intensity of 550 mW/cm^2. After storage in deionized water at 37°C for 24 hours, the diametral tensile strength was obtained using an Instron 4400R at a crosshead speed of 10 mm/min.

8.6.5 Radiopacity

The testing was based on ISO 4049:2009(E). The composite specimen was cured in stainless steel disk mold, 1 mm thick x 30 mm in diameter, using a Triad 2000 for 2 minutes on each side. Radiopacity of the restorative material was determined by comparing the optical density of a radiograph of a 1.0 mm thick cured material to that of a 0.5, 1, 1.5, 2.0, 2.5, 3.0 mm stepped standard aluminum block.

8.6.6 Water Solubility and Water Sorption

This test was based on ISO 4049:2009(E). The light cured specimens (1 mm thick by 15 mm in diameter) were transferred, to a desiccators maintained at 37°C. After 22 hours, the specimens were removed and stored in a second desiccator maintained at 23°C for 2 hours and then weighed. This cycle was repeated until a constant mass, m_1, was obtained. After the final drying, measurements were made of the diameter and the thickness in order to calculate the volume, V. The specimens were immersed in water at 37°C for 7 days in such a way that they are vertical, having a minimum of 3 mm separation between specimens. After 7 days, the specimens were removed, washed with water, surface water blotted until free from visible moisture, dried in the air for 15 seconds, and weighed 1 min. after removal from the water. This mass was recorded as m_2. After this weighing, the specimens were reconditioned to constant mass in the desiccator. Record the constant mass as m_3.

The values for water sorption, W_{sp}, were calculated using the following equation:

$$W_{\mathrm{sp}} = \frac{\mathrm{m}_2 - \mathrm{m}_3}{V}$$

The values for solubility, W_{sl}, were calculated using the following equation:

$$W_{\mathrm{sl}} = \frac{\mathrm{m}_1 - \mathrm{m}_3}{V}$$

8.6.7 Compatibility with Universal Composites

A 10 mm x 10 mm x 10 mm mold was used for this testing. A 4 mm bulk filled layer of SDR™ material was placed in the mold and cured for 20 seconds. Additional universal composite material was next incrementally filled and cured per DFU on top of the SDR™ material, up to a total of an additional 4 mm. The cured specimen

(10 mm x 10 mm x 8 mm in height) was stored at 37°C in deionized water overnight. Each specimen was then cut into 1 mm x 1 mm rods and tested for Micro-Tensile strength. Fifty specimens were tested for each material, including only those specimens that broke at the composite/flowable interface.

8.6.8 Color Stability

8.6.8.1 Water Storage

A circular mold, with internal dimensions 30 mm diameter x 1mm height, was placed on a Mylar covered glass plate and slightly overfilled with SDR™ composite. The second glass plate was positioned on top of a piece of Mylar covering the mold. The two plates and mold were secured together using binder clips and the composite was light cured in Triad 2000 for 2 minutes on each side. The specimens were removed from the molds. The initial color and opacity values were measured in the CIE L*a*b* scale on a Greta Macbeth Color-EYE 3100. The specimens were stored in deionized water at 37°C for different time and the total change in color, ∆E and opacity, were measured and calculated.

8.6.8.2 Ultraviolet Irradiation

A circular mold, with internal dimensions 20 mm in diameter and 0.5 mm in height, was placed on a Mylar covered glass plate and slightly overfilled with SDR™ material. The second glass plate was positioned on top of a piece of Mylar covering the mold. The two plates and mold were secured together using a binder clip and the composite was light cured with Spectrum 800 at a light intensity of 550 mW/cm^2 for 10 seconds on each quadrant, starting in the middle and then overlapping clockwise until the whole chip area had been cured. Specimen 1: After removal from the mold, the specimen was stored in the dark, dry in the oven at 37°C for 7 days. This is the standard specimen. Specimen 2: After removal from the mold, the specimen was stored in the dark, dry in the oven at 37°C for 24 hrs. After this time, specimen 2 was removed from the oven and half of it was blanked off using aluminum foil. Specimen 2 was next immersed in water at 37°C, placed in a Heraeus Suntest unit, and exposed to UV radiation for 24 hrs. After exposure, the metal foil was removed. Specimen 2 was transferred back to the oven at 37°C and stored in the dark, dry for 5 more days. The color of both halves of specimen 2 was compared with each other and with the standard specimen 1. The color comparison was carried out in accordance with ISO 7491.

Results:
When compared to the standard specimen, no noticeable color change was observed with SDR™ restorative universal shade of among the specimens stored at the specified conditions.

8.6.9 Fluoride Release

Fluoride ion release was determined using an Accumet® AR50 Dual Channel pH/Ion/Conductivity Meter with a Fluoride ion electrode. Disc samples of the composite, 1 mm thick by 20 mm in diameter, were immersed in 20 ml of deionized water for one-week intervals. The Fluoride ion content of the solution was determined until the reading was below 0.1 ppm. The cumulative Fluoride ion release is determined by adding the weekly Fluoride ion release to that of the previous week. Two specimens were prepared and measured. The average value was recorded.

9 References

Blaes J, 2008, Dental Economics, June, Vol. 98, No. 6.

Condon J et al, 2000, “Assessing the Effects of Composite Formulation on Polymerization stress”, J Am Dent Assoc, Vol. 131, No. 4, pp 497-503.

Latta MA, 2007, “Shear Bond strength and physicochemical interactions of XP Bond”, J Adhes Dent, Vol. 9, pp 245-248.

Eichmiller FC, 2004, “Polymer Shrinkage Tensometer”, US Patent 6,871,550, March 29, 2004.

Ernst C-P, Busemann I, Schattenber A, Willershausen B, 2009, “Determination of polymerization shrinkage stress in low shrinkage resin composites using an improved cavity design”, Data on File.

Feilzer, AJ, et al. 1987, “Setting stress in composite resins in relation to configuration of the restoration”, J Dent Res, Vol. 66, pp 1636-1639.

Ferracane JL, 2008, “Glass Ionomer liner Reduces Contraction Stress”, Operative Dentistry, Vol. 33, No. 3, pp 247-257.

Frankenberger R, et. al., 2008, “Luting of ceramic inlays in vitro: Marginal quality of self-etch and etch-and-rinse adhesives versus self-etch cements”, Dental Materials, Vol 24, pp 185-191.

Frankenberger R, 2008, Data on File.

Frankenberger R, Tay FR, 2005, “Self-etch vs. Etch-and-rinse adhesives; effect of thermo-mechanical fatigue loading on marginal quality of bonded resin composite restorations”, Vol. 21, No. 5, pp 397-412.

Ilie N, 2007, “Study Report, DENTSPLY 2007”, Data on File.

Lu H, Stansbury JW, Dickens SH, Eichmiller FC, Bowman CN, 2004, “Probing the origins and control of shrinkage stress in dental resin-composites”, J Mat Sci Mater Sci Med, Vol. 15, No. 10, pp 1097-1103.

Peutzfeldt A, 1997, “Resin composites in dentistry: the monomer systems”, Eur J Oral Sci, Vol. 105, No. 2, pp 97-110.

Reis A, 2009, “Depth of Cure analysis of a novel composite restorative system for posterior teeth”, Data on File.

Reis A, 2009, “Evaluation of a novel composite restorative system for posterior teeth: microleakage, bond strength, and gap formation analysis (Class I Cavities)”, Data on File.

Reis, A, 2009, “Evaluation of a novel composite restorative system for posterior teeth: microleakage, bond strength, and gap formation on Class II MOD cavities”, Data on File.

Tay FR, Pashley DH, Yoshiyama M, 2002, “Two modes of nanoleakage expression in single step adhesives, J Dent Res, Vol. 81, pp 472-476.

Truffier-Boutry D, et al, 2006, “A physic-chemical explanation of the post-polymerization shrinkage in dental resins”, Dent Mater, Vol. 22, No. 5, pp 405-412.

Yamazaki PC et al, 2006 “Microleakage Evaluation of a New Low-Shrinkage composite Restorative Material”, Operative Dentistry, Vol. 31, No. 6, pp 670-676.

10 Glossary and Abreviatons

ATR	Attenuated Total Reflectance
IFU	Instructions for Use
E&R	Etch&Rinse Etching with phosphoric acid which has to be rinsed off (formerly referred to as Total Etch Technique)
FTIR	Fourier Transform Infra-Red Spectrometry
LED	Light Emitting Diode
NIR	Near Infrared analysis
NIST	National Institute of Standards and Technology
QTH	Quartz Tungsten Halogen
SBS	Shear Bond Strength
SDR	Smart Dentin Replacement Stress Decreasing Resin
SEM	Scanning Electron Microscope
TC	Thermo Cycles, Cycling
TML	Thermo Mechanical Loading
VAS	Visual Analogue Scale

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The following materials are not trademarks of DENTSPLY International.

Brand (abbreviation, Manufacturer):

Adper Prompt L-Pop (3M ESPE)
Beautifil Flow Plus (Shofu)
Clearfil Majesty Flow (Kuraray)
Clearfil Majesty posterior (CFM Post, Kuraray)
ELS (Saremco)
Empress II (Ivoclar Vivadent)
Estelite Sigma Quick (Tokuyama)
Excite DSC (Ivoclar Vivadent)
Filtek Supreme Plus (3M ESPE)
Filtek Supreme Plus Flowable (FS flow, Filtek SP flow, 3M ESPE)
Filtek Supreme Ultra Flowable (3M Espe)
Filtek Supreme XT (F Sup XT/Filtek Supr. XT, 3M ESPE)
Filtek Supreme XT flow (F Sup XT flow, Filtek SP flow, Filtek Supr. Flow, 3M ESPE)
Filtek Silorane (3M ESPE)
Filtek Z100 (3M ESPE)
Filtek Z250 (3M ESPE)
G-aenial Flo (GC)
G-aenial Universal Flo (GC)
Grandio (Voco)
Grandio Flow (Voco)
GrandiO SO Heavy Flow (VOCO)
Herculite XRV (Kerr)
iBond SE (Heraeus)
Point 4 (Kerr)
Premise (Kerr)
Premise Flow (Kerr)
Revolution Form 2 (Kerr)
Scotchbond 1 XT (SB1XT, SB, 3M ESPE)
Syntac (Ivoclar Vivadent)
Tetric EvoCeram (Ivoclar Vivadent)
Tetric Evoflow (Ivoclar Vivadent)
Venus (Heraeus)
Venus Bulk Fill (Heraeus Kulzer)
Venus Diamond (Heraeus)
Venus Diamond Flow (Heraeus Kulzer)