Science.
Applied to Life.™

3M & Bioclear Restorative Solutions

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BIOCLEAR

Biofilm Removal

Bioclear Method for 3M Composite Restorations

Preparation Design

- Designed for composite
- Minimizes stress concentration
- Maximizes enamel involvement

Bioclear Matrices

- Anterior & Posterior Matrices designed to mimic nature

Warm Injection Molded Composite

- Injection mold warmed 3M™ Filtek™ Restorative materials

Biofilm Removal

- Remove biofilm before bonding
- Allows bonding to uncut enamel
- Allows infinity edge margins

Systematic restorative protocol designed for esthetic clinical outcomes

Final Polish

- 3M™ **Sof-Lex™ XT coarse discs for reduction**
- **"Rock Star" polish with Bioclear Magic Mix & RS Polisher**

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Biofilm Adhesive Study

Protocol in Development

Indiana University School of Dentistry

Dental Biomaterials

Indianapolis, Indiana

Study Director

Sabrina F. Sochacki, DDS, MS, PhD

Department of Biomedical and Applied Sciences

Study number: 19-V-002

Title: Effect of a new enamel surface treatment protocol, using a biofilm remover and a resin-composite preheating technique, on the bond strength to resin composite.

Study Sponsor
3M ESPE
Attention: Jean Madden
Scientific Affairs Manager

Contract Laboratory
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Dental Biomaterials
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PROTOCOL

Objectives
To evaluate the effect of a new enamel surface treatment protocol, using a biofilm remover and a resin-composite preheating technique, on the bond strength to resin composite.

Background:
One of the goals of restorative dentistry is to achieve a proper adaptation between the restorative material and the enamel/dentin substrate [1, 2], avoiding the presence of gaps in this interface [1]. The presence of residual biofilm after preparation can compromise the bonding between the substrate and restoration [1]. Therefore, it is important to ensure that the enamel/dentin substrate is properly cleaned before the resin application. In addition to biofilm removal, application of a preheated resin composite is a complementary method to reducing gaps at the restorative interface. According to the literature, preheating resin composites decreases their viscosity, reduce polymerization shrinkage, maintain the degree of conversion without affecting selected materials

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Preparation Design

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Comparing Conventional and Saucer-Shaped Composite Restoration Designs

	Objective	Title
Study #1	Determine volume of enamel and dentin removed based on cavity design.	Micro-CT Volumetric Analysis of Cavity Preparations
Study #2	Simulation of shrinkage and occlusal stresses and fracture of restorations of different cavity designs.	Finite Element Analysis of Shrinkage and Occlusal Stresses and Fracture
Study #3	Determine if cavity design affects the adaptation and internal defects of composite restorations.	Micro-CT Analysis of Defects in Restorations
Study #4	Determine fracture load of model restorations of different cavity designs.	Mechanical Testing of Restored Typodont Teeth

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Minnesota Dental Research Center for Biomaterials & Biomechanics

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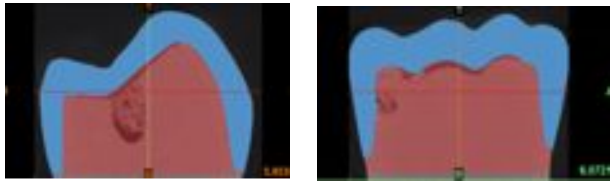
Study #1 | Volumetric Analysis of Cavity Preparations

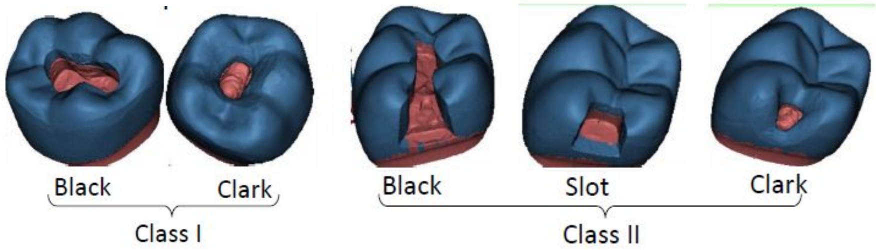
Step 1

5 Typodont Teeth with Simulated Class I and Class II Caries are scanned with a Micro CT



Step 2

The typodont teeth prepared by
Dr. Jihyon Kim, DDS*



Step 3

Teeth re-scanned to measure the volume of dentin and enamel removed

*Former Co-Director of the Bioclear Leaning Center

Cavity Designs	Enamel Loss (mm^3)	Dentin Loss (mm^3)	Total Loss (mm^3)
G.V. Black Class I	21 (32%)	43 (68%)	63
Clark Class I	9 (42%)	13 (58%)	22
G.V. Black Class II	31 (40%)	47 (60%)	77
Slot Prep Class II	12 (25%)	38 (75%)	51
Clark Class II	9 (24%)	29 (76%)	38

Results

Class I — G.V. Black preparations resulted in 3x the total tooth structural loss compared to the Clark Class I.

Class II — G.V. Black preparations resulted in 1.5 to 2x the total tooth structural loss compared to Clark and Slot designs .

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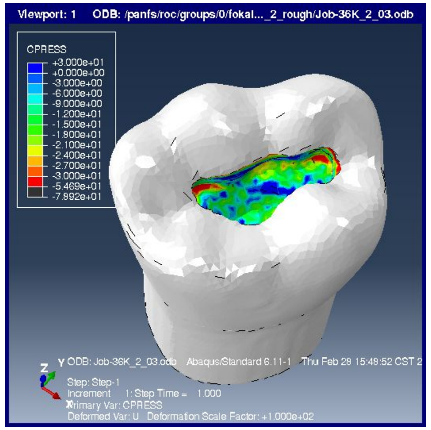
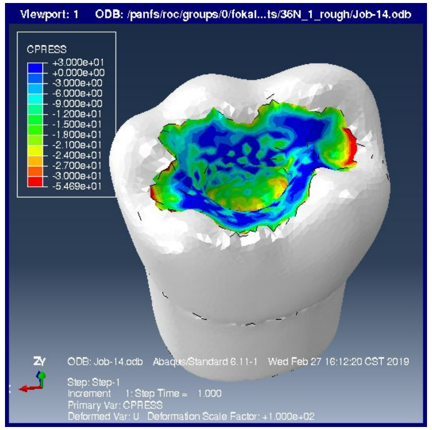
Study #2 | FEA Computer Model: Class I Shrinkage Stress

Class I Interfacial shrinkage stress contours



G.V. Black Class I

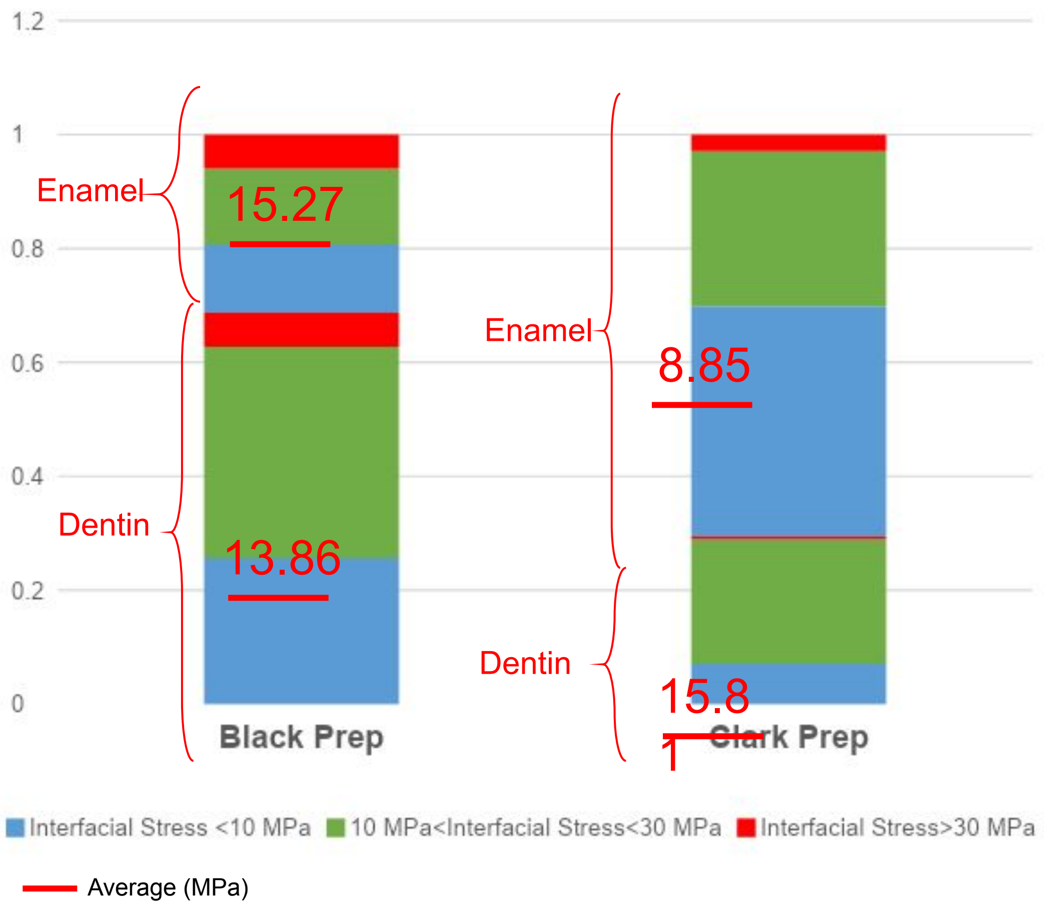


Clark Class I

Results:

- Within enamel, the average interfacial stress is less tensile in the Clark design than the G.V. Black design.
- The Clark design has compressive stresses at the bevel near the cavosurface margin.
- The average interfacial stress within dentin is slightly more tensile in the Clark design.

Distribution of normal stress over interfacial area.



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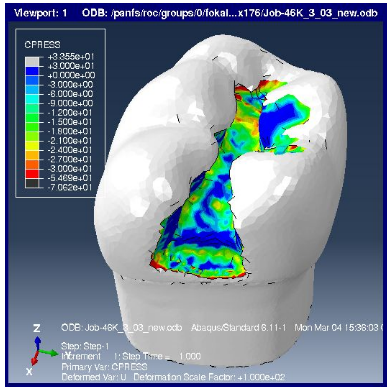
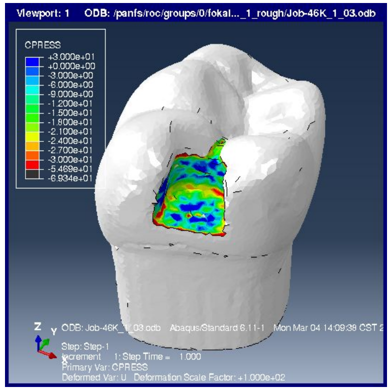
Study #2 | FEA Computer Model: Class II Shrinkage Stress

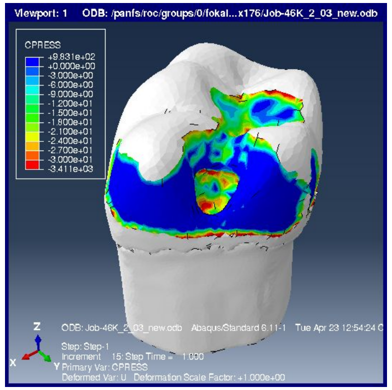
Class II Interfacial shrinkage stress contours



G.V. Black Class II



Slot Class II

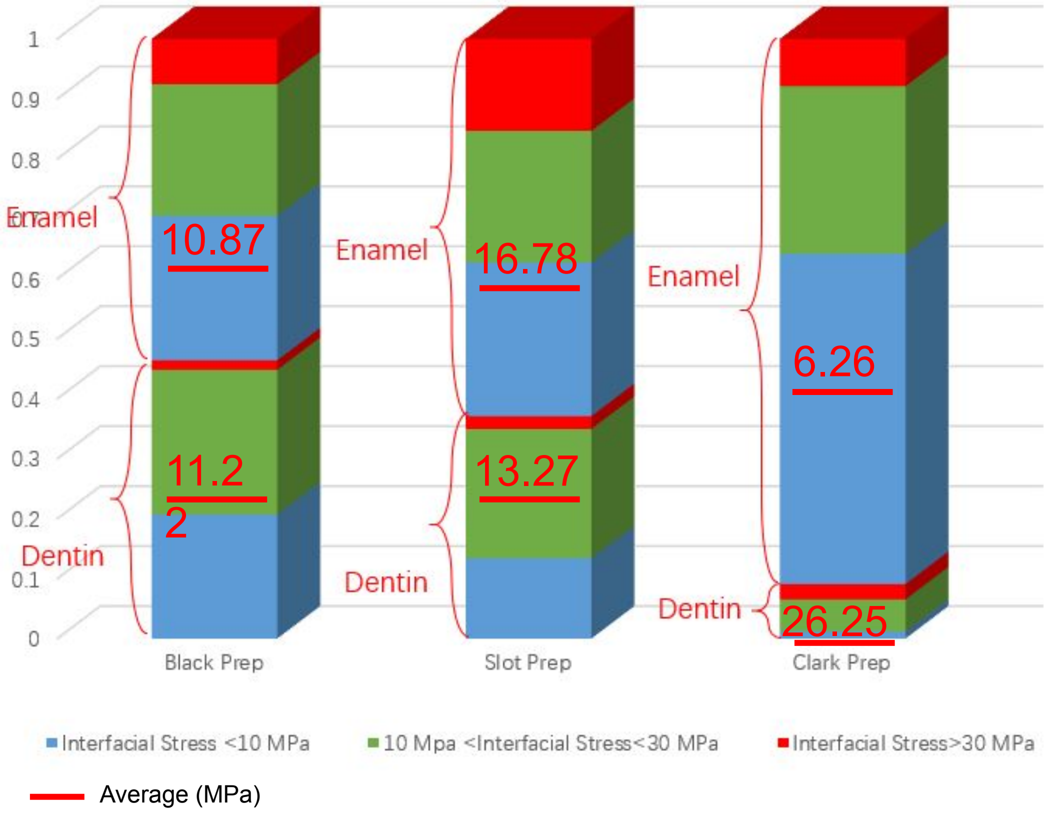


Clark Class II

Results:

- **The Clark Class II,** with saucer-shaped internal surfaces and broad enamel bevel, **produced less tensile shrinkage stresses in enamel (which can cause debonding) than the G.V. Black or Slot cavity preparation designs.**
- The average **interfacial stress within dentin** in the **Clark design** is roughly **twice as tensile** as in the Slot or G.V. Black design.

Distribution of normal stress over interfacial area



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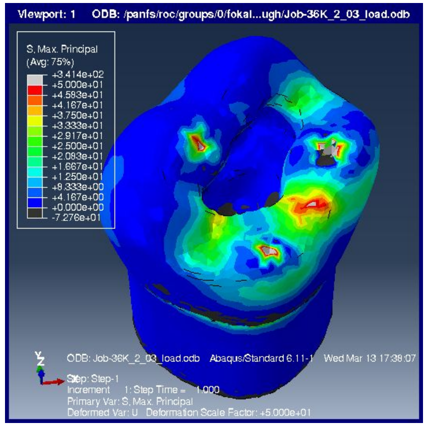
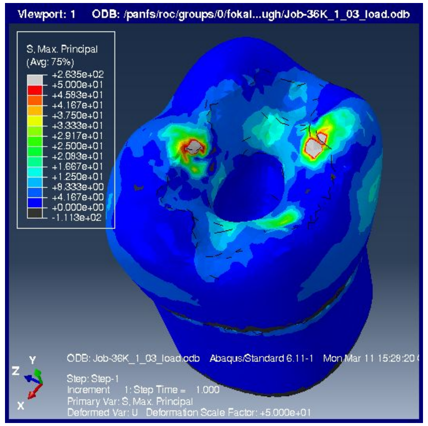
Study #2 | FEA Computer Model: Class I Cohesive Stresses due to Occlusal Loading (2000 N)

Class I Max principal stress contours due to occlusal loading (without displaying the restoration)

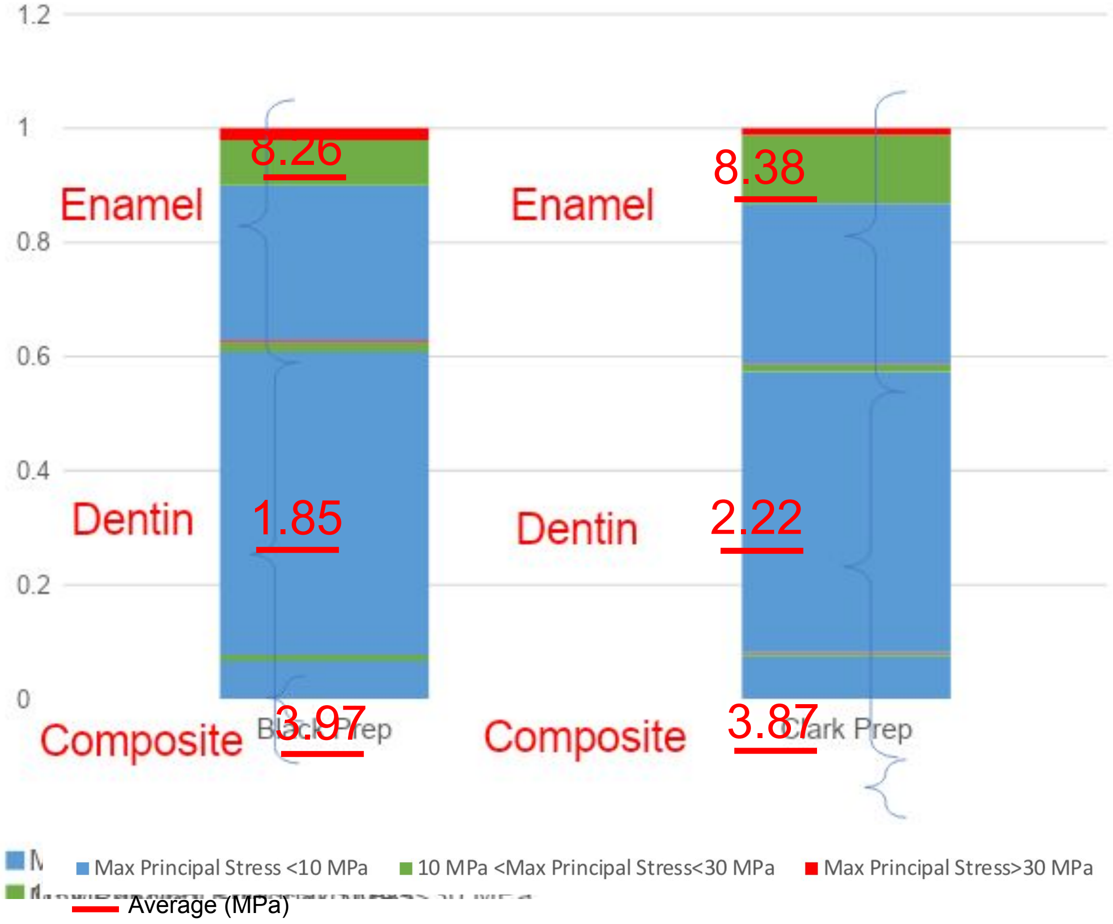




Results:

- The average maximum principal stress of the two cavity designs are similar in enamel, dentin and composite.
- Higher tensile **stresses on the enamel surface of the G.V. Black design potentially making it more vulnerable to fracture by occlusal load.**

Distribution of Maximum Principal Stress within volume



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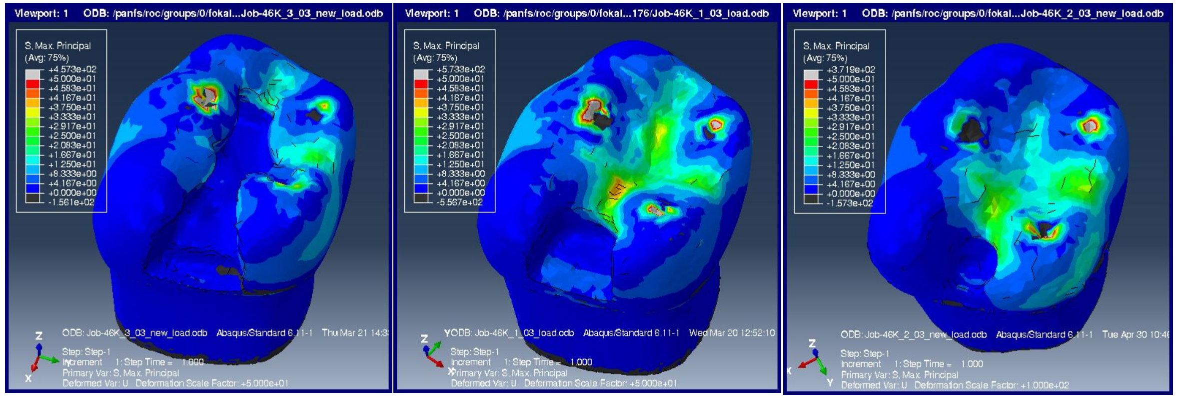
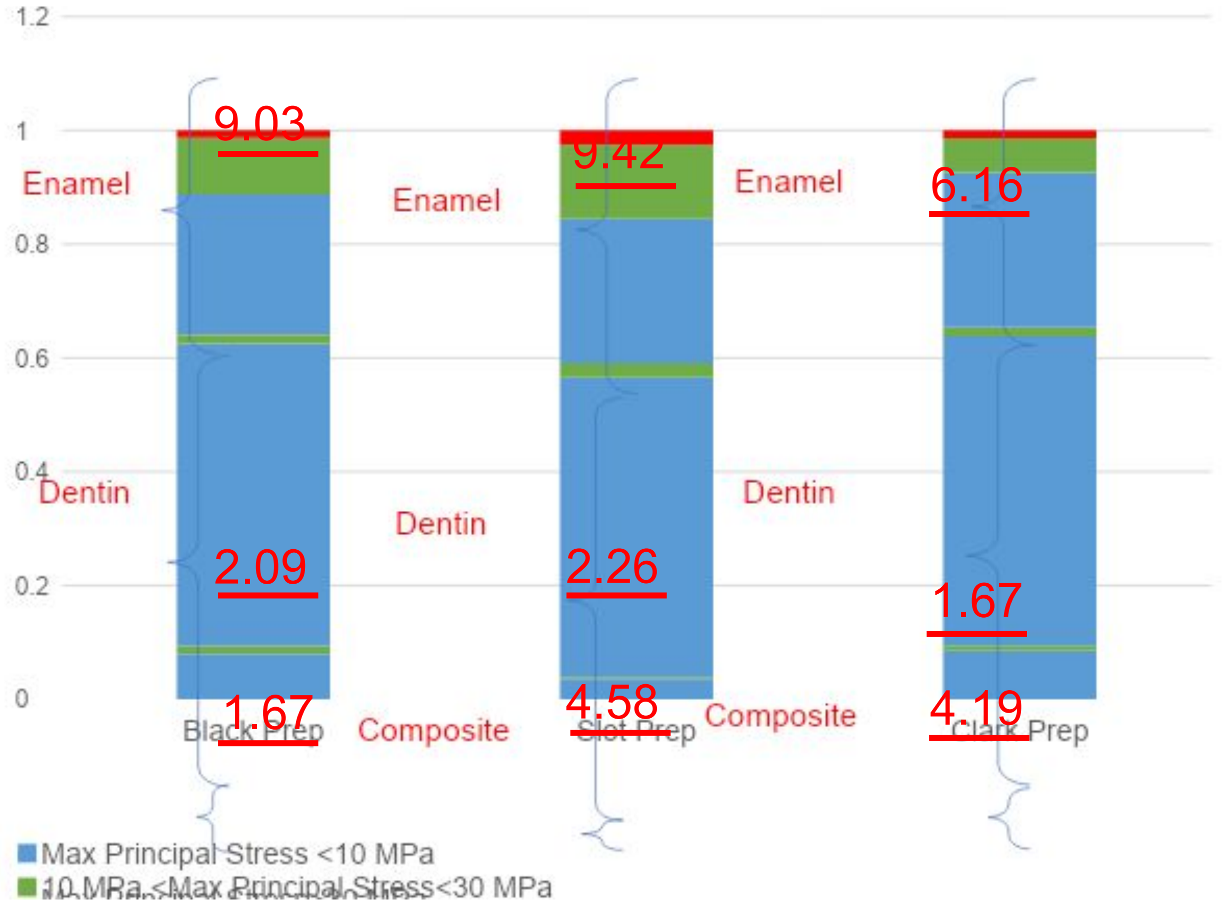
Study #2 | FEA Computer Model: Class II Stresses due to Occlusal Loading (2000 N)





Results:

The Clark Class II design has, on average, lower maximum principal stress in enamel and dentin but higher or similar maximum principal stress in the composite.

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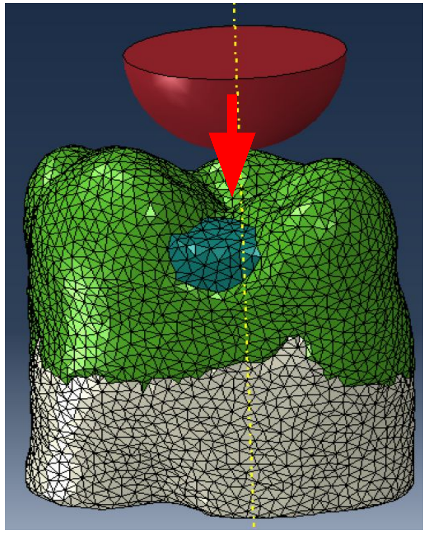
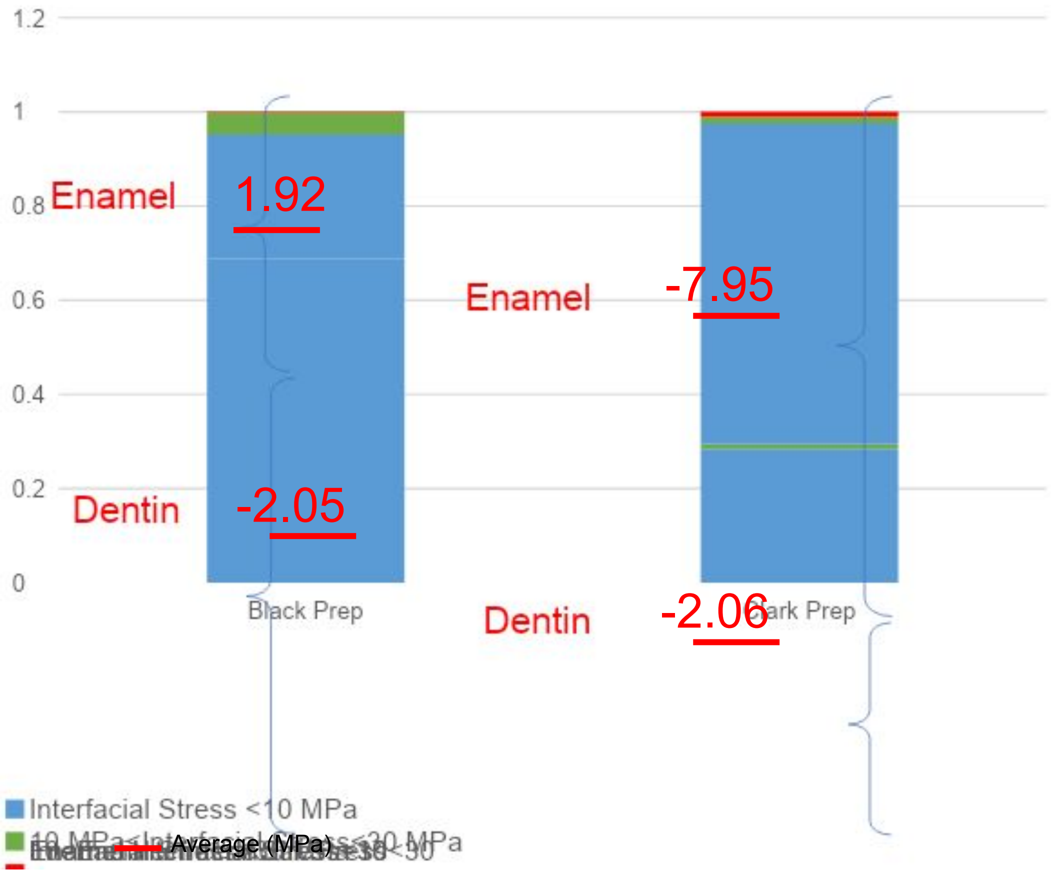
Study #2 | FEA Computer Model: Class I Interfacial Stresses due to Occlusal Loading (2000 N)



Occlusal stress is simulated in a **Class I restoration** by adding a hemisphere as an antagonist to the occlusal surface with downward vertical force, resulting in three occlusal contact points.

Distribution of Interfacial Normal Stress over the area of tooth-restoration interface



Results:

- The stresses at the composite-dentine interface are similar between the two designs.
- **Stresses at the composite-enamel interface are more tensile in the G.V. Black design, potentially making it more vulnerable to debonding under occlusal loading.**

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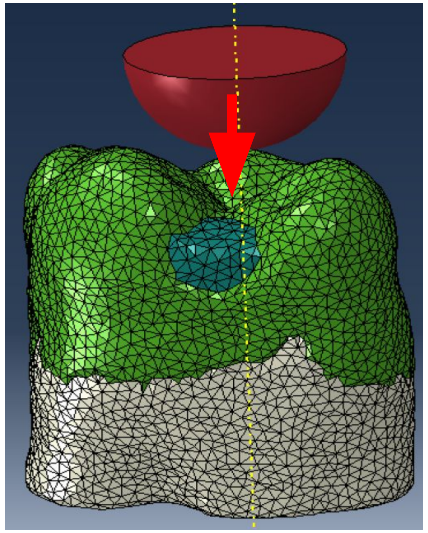
Study #2 | | FEA Computer Model: Class II Interfacial Stresses due to Occlusal Loading (2000 N)

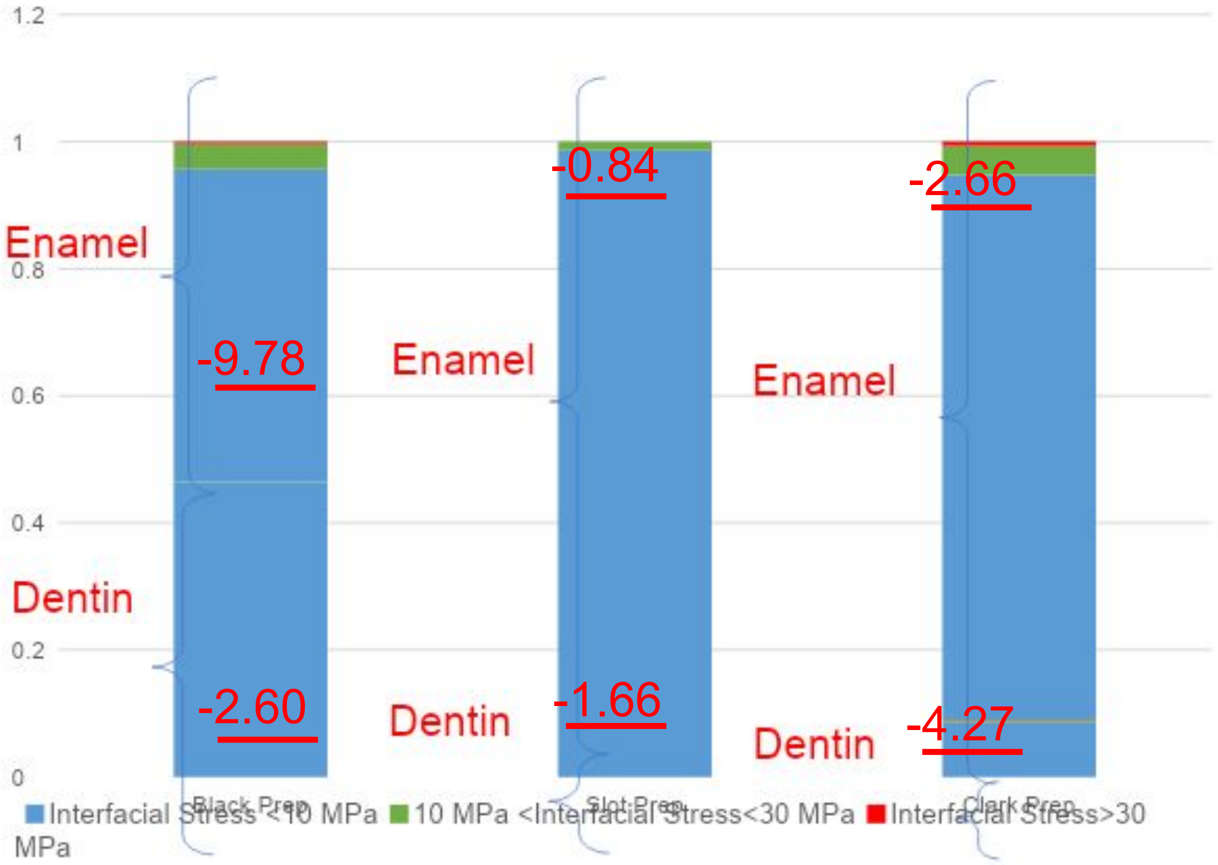


Occlusal stress is simulated in a **Class II** restoration by adding a hemisphere as an antagonist to the occlusal surface (2000 N) with downward vertical force, resulting in three occlusal contact points.

Results:

- The proportion of composite-enamel interfacial area with the higher tensile stresses (> 10 MPa) is highest in the G.V. Black design, followed by Clark and Slot.
- Interfacial stresses at the composite-dentin interface are mostly compressive in all 3 designs.

Distribution of Interfacial Normal Stress over the area of tooth-restoration interface



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Study #3 | Defect Analysis using MicroCt

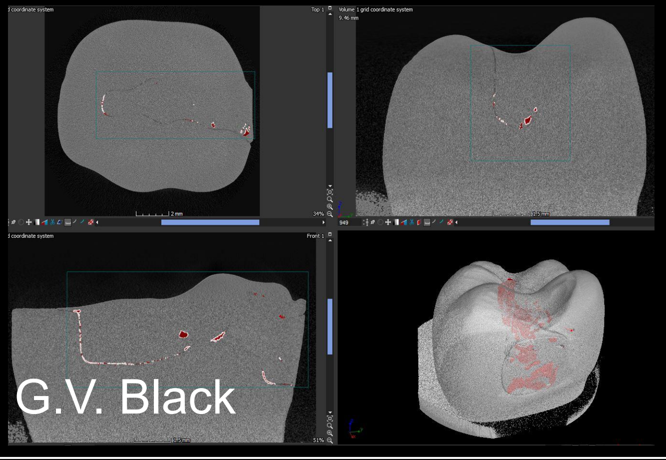
5 dentists experienced with both injection molding and layering techniques restored 2 teeth from each group listed below.

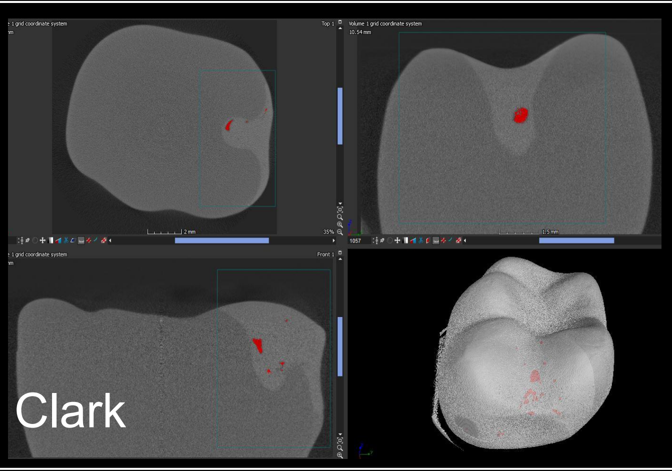
Groups	Restoration Technique	Finishing	Matrix System	Mean Total Volume of Voids (mm^3)
Black Class II	room temperature layered composite	Butt joint	Tofflemire	0.47 ± 0.16
Clark Class II	warmed uncured flowable composite co-cured with warmed monolithic bulk-fill composite	Infinity margin	Biofit HD 5.5mm	0.08 ± 0.07
Clark Class II with (Uncured Adhesive)	uncured adhesive as a surfactant, warmed uncured flowable composite co-cured with warmed monolithic bulk-fill composite	Infinity margin	Biofit HD 5.5mm	0.07 ± 0.08

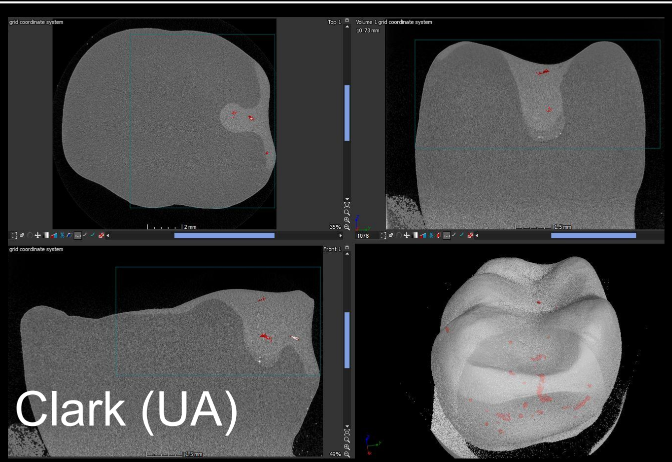
Results:

The G.V. Black restoration had noticeable interfacial debonding and roughly 2x the amount of defects compared to the two Clark restoration groups.

* One-Way ANOVA was used to compare the groups and groups with different letters are significantly different







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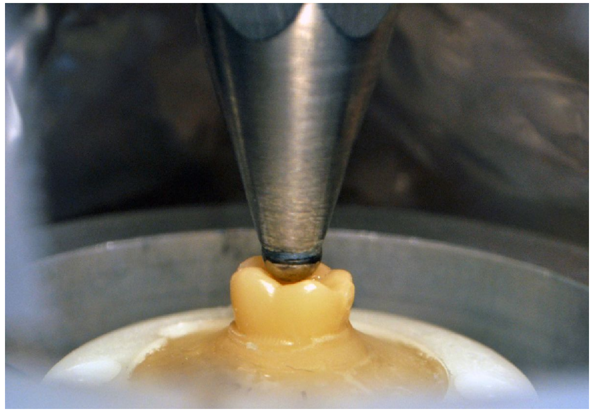
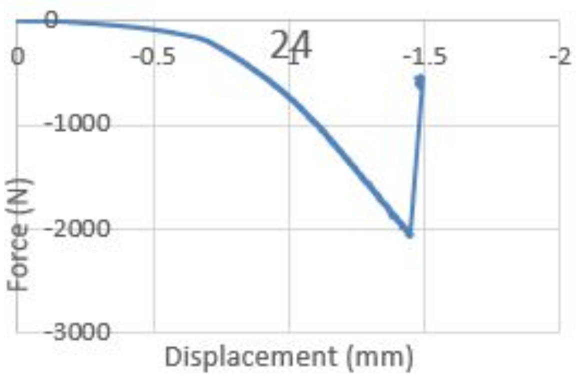
Study #4 | Mechanical Testing of Restored Typodont Teeth

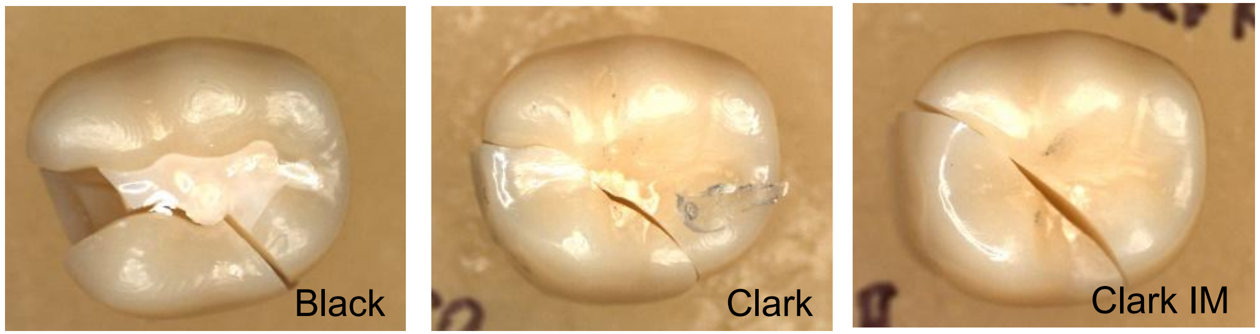
The 30 samples created for Study #3 (defect analysis) were subjected to fracture testing.

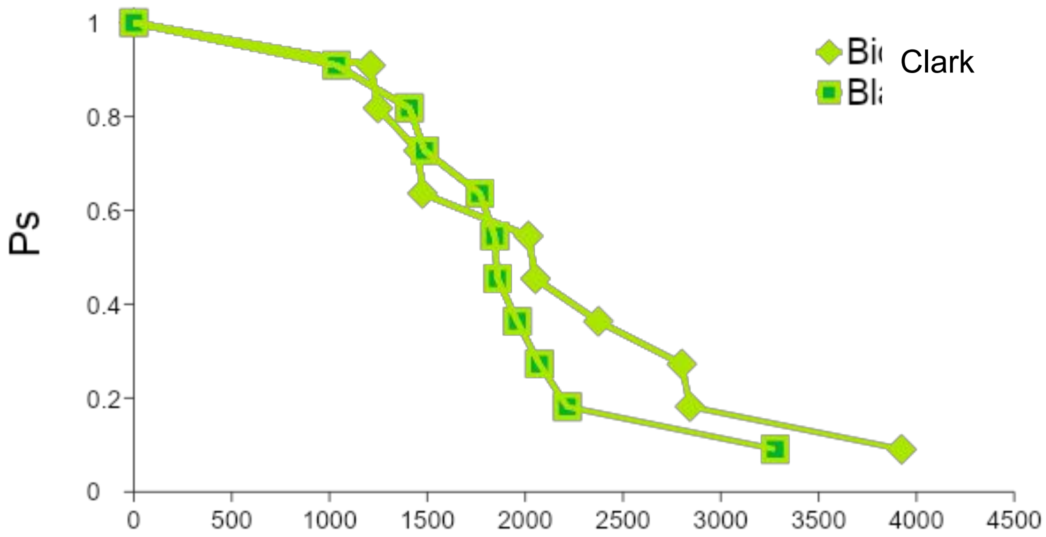




N=10	Black	Clark	Clark IM
Fracture Force (N)	1893 ± 598	2141 ± 867	2176 ± 557

One-Way ANOVA was used to compare the groups and there are no significant differences among the groups





Results:

- G.V. Black and the Clark groups had similar failure rates at low loads.
- The Clark group had lower failure rates at higher loads.

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Stress Related to Preparation Design

Conculusion

"It can be concluded that the cavosurface angle studied influenced the marginal gap formation and the stress concentration.

The smallest stresses were found at cavosurface angles of 120˚ or 135˚.

Overall, the study suggested that marginal gap formation is strongly related to the cavosurface angles of the cavity."

Journal of the Mechanical Behavior of Biomedical Materials 97 (2019) 272–277

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

ELSEVIER

Influence of cavosurface angle on the stress concentration and gaps formation in class V resin composite restorations

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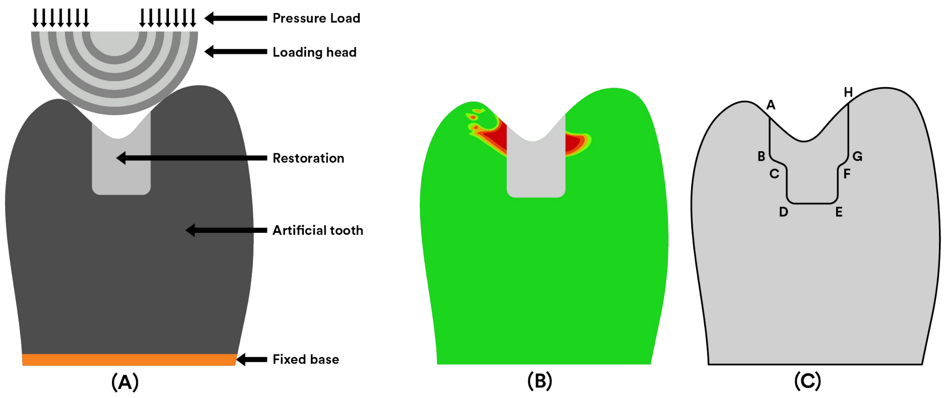
Increasing Resistance to Composite Debonding

Significance

> Cavity shape optimization can help increase the debonding resistance of restored teeth by reducing the interfacial stresses between tooth and restoration under occlusal load.



DENTAL MATERIALS 26 (2010) 126–134

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ELSEVIER

Strengthening of a model composite restoration using shape optimization: A numerical and experimental study

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ARTICLE INFO

Article history:
Received 8 July 2009
Received in revised form
1 September 2009

ABSTRACT

Objective. This study aims to validate a cavity shape optimization approach for improving the debonding resistance of dental restorations by carrying out fracture tests on restored model teeth with standard and optimized cavity designs.
Method. The bio-mimetic stress-induced material transformation (SMT) optimization

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Bioclear Mylar Matrices

featuring BIOCLEAR

Advantages of Mylar Matrices

In the absence of human saliva, mylar matrix strips promoted the lowest bacterial adhesion to 3M™ Filtek™ Supreme Ultra Universal Restorative.

In the presence of saliva, Filtek Supreme Ultra Universal Restorative exhibited the lowest bacterial adhesion when no finishing or polishing was performed.

CA Pereira, E Eskelson, V Cavalli, PCS Liporoni, AOC Jorge, and MA do Rego (2011), *Streptococcus mutans* Biofilm Adhesion on Composite Resin Surfaces After Different Finishing and Polishing Techniques. Operative Dentistry: May/June 2011, Vol. 36, No. 3, pp. 311-317.

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Warm Injection Molding

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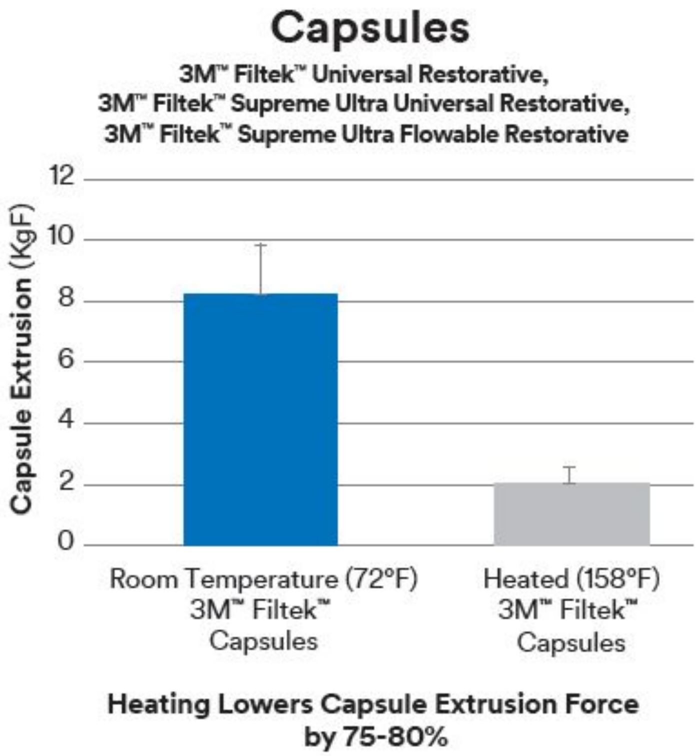
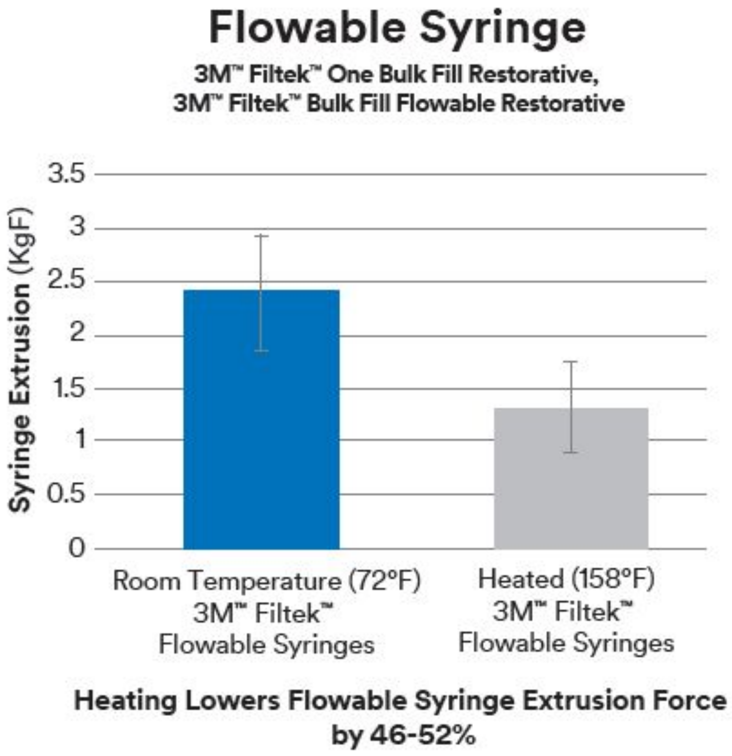
Why Warm?

- ☑ Warm composites are more fluid for easier handling
- ☑ Lowers extrusion force[(1)]
- ☑ May improve adaptation of 3M composite to tooth structure [(2)]

Lower Extrusion Force



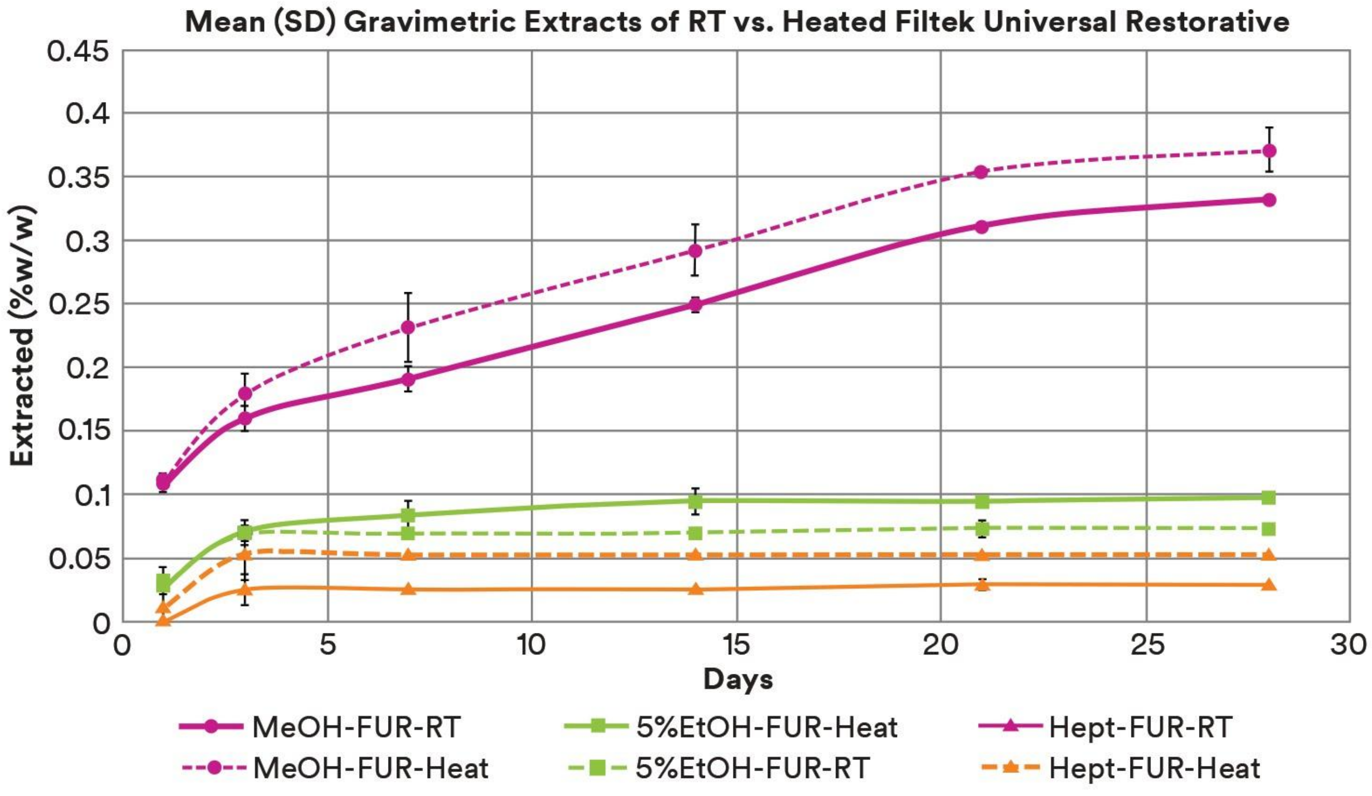


(1) 3M Internal Data

(2) Based on a 3M sponsored *in vitro* study. 11 dentists placed 88 Class II MOD restorations. Typodont teeth were microscopically exampled for flaws, defects and voids. Comparisons made between techniques and operators.

14% of dentists survey stated they use some type of device to warm their composite prior to placement.

Safely Warm — Biocompatibility Assessment



Conclusions

There were no statistical differences between the room temperature (RT) and heated (Heat) 3M™ Filtek™ Universal Restorative* as far as the relative amount of material extracted from warmed and non-warmed, light-cured samples.

Where differences existed, thresholds of toxicological concern were not exceeded therefore warming Filtek Universal Restorative is safe.**

* 3M™ Filtek™ Supreme Ultra, 3M™ Filtek™ Supreme Ultra Flowable, 3M™ Filtek™ One Bulk Fill and 3M™ Filtek Bulk Fill Flowable Restoratives can also be safely warmed.

** According to a biocompatibility assessment performed by a board-certified toxicologist in accordance with ISO 10993 and ISO 7405.

Gravimetric Extraction of Warmed and Room Temperature Experimental Composite, T. Dunbar et. al., *J Dent Res* Vol #98A, Abstract #1877, 2019

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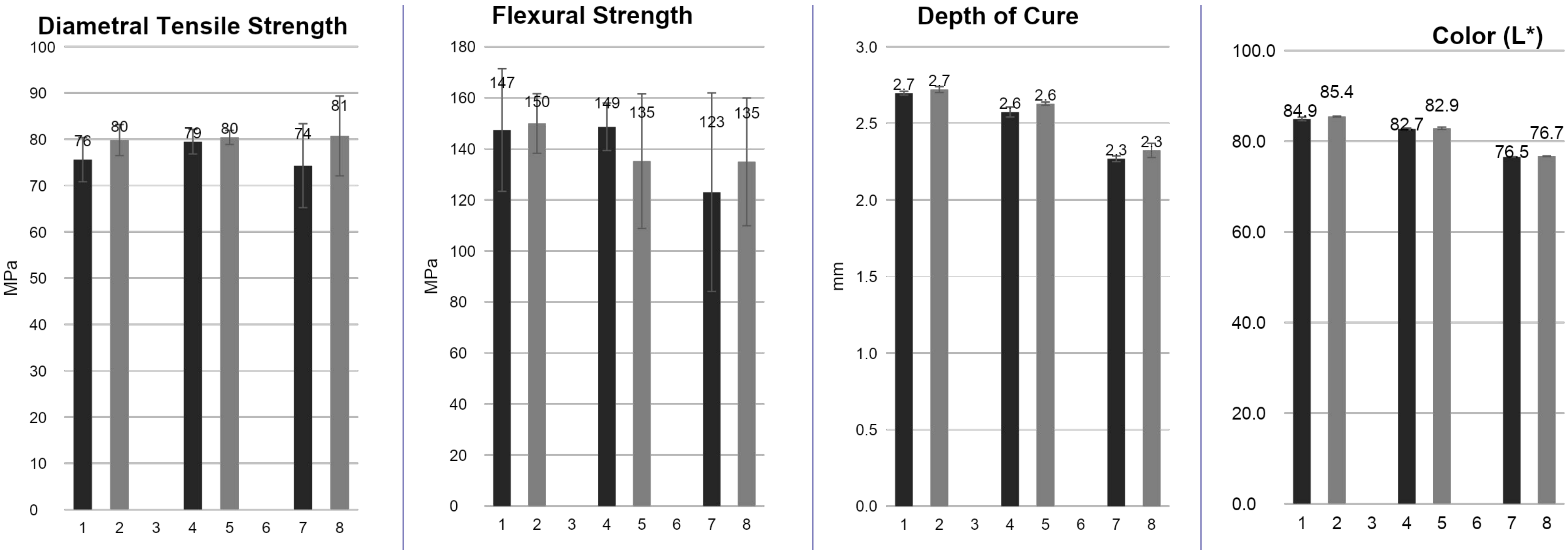
Physical Properties Unchanged



Physical and Esthetic Properties of a Warmed Dental Composite, M. Agre et. al., *J Dent Res* Vol #98A, Abstract #1670, 2019

3M™ Filtek™ Universal Restoratives have the same physical properties when used warmed or at room temperature*

* 3M™ Filtek™ Supreme Ultra, 3M Filtek™ Universal, 3M™ Filtek™ Supreme Ultra Flowable, 3M™ Filtek™ One Bulk Fill and 3M™ Filtek Bulk Fill Flowable Restoratives.

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Effect of Preheating and Fatiguing/Thermocycling on Mechanical Properties

3M™ Filtek™ Supreme Ultra Universal Restorative 	Fracture Toughness $(MPa.m^{1/2})$	Flexural Strength (MPa)	Diametral Tensile (MPa)	Young's Modulus (GPa)
Room Temperature (RT)	1.53 ± 0.21	150.74 ± 11.52	62.05 ± 5.06	15.17 ± 0.73
Heated	1.57 ± 0.13	144.33 ± 7.00	64.90 ± 7.74	13.74 ± 1.35

3M™ Filtek™ One Bulk Fill Restorative 	Fracture Toughness $(MPa.m^{1/2})$	Flexural Strength (MPa)	Diametral Tensile (MPa)	Young's Modulus (GPa)
Room Temperature (RT)	1.78 ± 0.13	149.40 ± 13.66	55.74 ± 3.34	16.46 ± 1.4
Heated	1.94 ± 0.16	161.42 ± 4.40	59.69 ± 6.70	14.15 ± 2.03

Conclusions

Pre-heating had no significant effect on Fracture Toughness, Flexural Strength or Diametral Tensile Strength.

Warmed to 68°C

Fatiguing and Preheating Effect on Mechanical Properties of Composite Resins, A. Abdulmajeed et. al., *J Dent Res* Vol #98A, Abstract #1879, 2019

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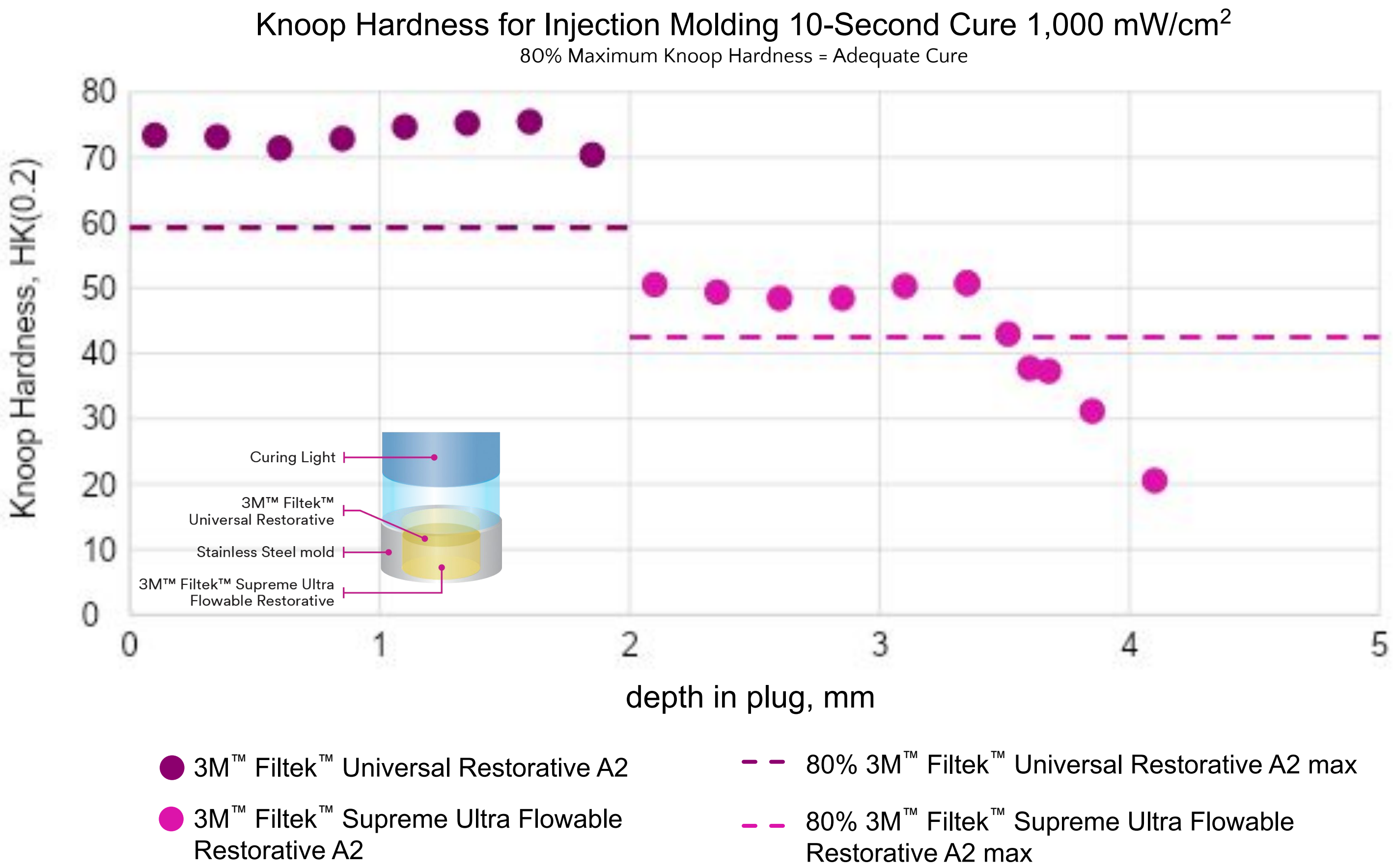
Injection molding | Curing & Adhesion Validation

Video courtesy of Dr. David Clark

Can a Flowable be Cured Beneath an Incremental/Bulk-Fill Resin-Based Composite?, T. Dunbar et. al., *J Dent Res* Vol #98A, Abstract #2906, 2019



Any shade of 3M™ Filtek™ Universal Restorative (excluding PO) can be co-cured with any shade of 3M™ Filtek™ Supreme Ultra Flowable Restorative to a total depth of 2 mm with adequate adhesion.

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Comparison of Class II Adaptation & Placement Times

Materials & Techniques Tested

Temperature	Technique	Matrix	Products
Room Temperature	Layered	SuperMat™	Universal Composite 
Room Temperature	Bulk Fill	Biofit	3M™ Filtek™ One Bulk Fill Restorative 
Warmed (68C)	Bulk Fill	Biofit	3M™ Filtek™ One Bulk Fill Restorative 
Warmed (68C)	Injection Molding	Biofit	3M™ Filtek™ One Bulk Fill Restorative 3M™ Filtek™ Bulk Fill Flowable Restorative 

Study Overview

- 11 dentists trained and calibrated.
- Placement of 4 class II MOD cavities (x2) with 5mm deep proximal boxes in heated typodont teeth.
- 88 restorations placed in total.

Dr. Richard Price, BDS, DDS, MS, FDS RCS, FRCD(C), PhD
Dept. of Clinical Dental Sciences & Biomedical Engineering
Dalhousie University

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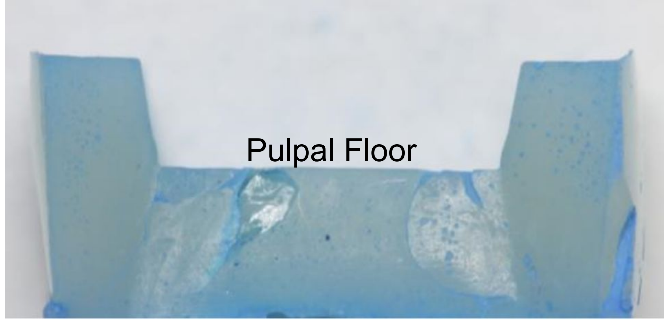
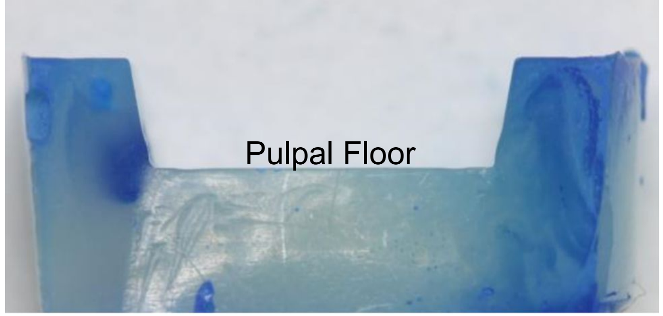
Comparison of Class II Adaptation & Placement Times

Results

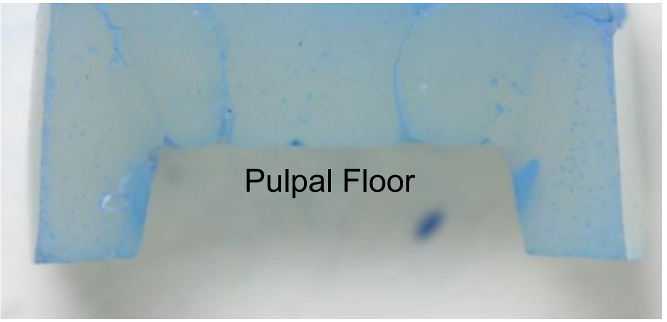
Layered, Room Temperature Universal Composite

Heated, Injection Molded 3M™ Filtek™ Bulk Fill Flowable and 3M™ Filtek™ One Bulk Fill Restorative



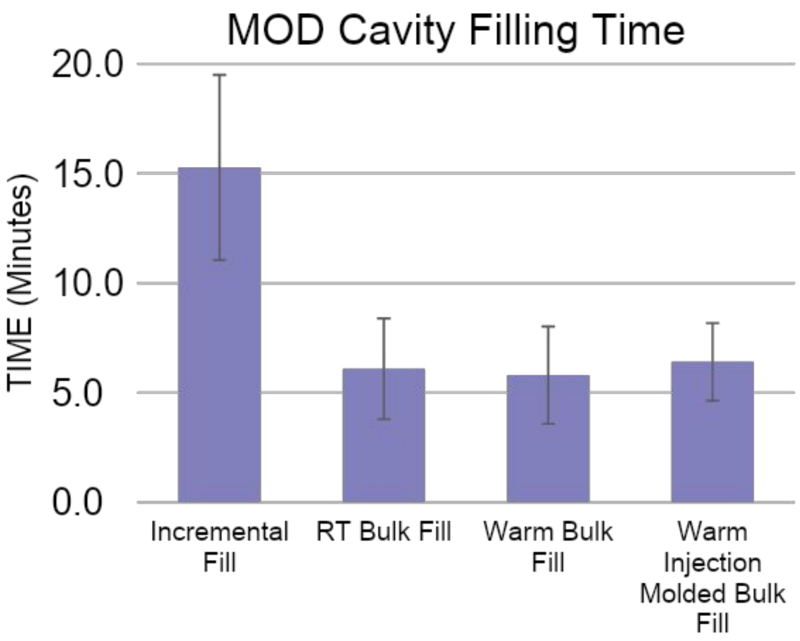


Dentist 6 – Sample #1



Dentist 6 – Sample #2

Time



Bulk filling is an average of 39% faster than traditional layering.

Injection molding (flowable + paste) did not significantly increase the average placement time ($p>0.01$).

Conclusion: Of the four methods tested, **warm injection molded 3M™ Filtek™ One Bulk Fill Restorative with 3M™ Filtek™ Bulk Fill Flowable** Restorative **provided the best adaptation, least voids and fewest lines between layers of composite** while being **9 minutes faster to place** than room temperature layered composite.

featuring BIOCLEAR

3M Product Summary

In support of the Bioclear Method, 3M has validated it is safe to warm the following Filtek™ products

Testing Complete and Safe to Warm Capsules

3M™ Filtek™
Universal Restorative

3M™ Filtek™ Supreme Ultra
Universal Restorative

3M™ Filtek™ One Bulk
Fill Restorative

Testing Complete and Safe to Warm Syringes

3M™ Filtek™ Supreme Ultra Flowable Restorative

3M™ Filtek™ Bulk Fill Flowable Restorative

A board-certified toxicologist, according to ISO 10993-1:2018, found that it was safe to <u>warm capsules</u> up to 70ºC/158ºF/up to 1 hour and <u>warm flowable syringes</u> up to 70ºC/158ºF/up to 1 hour/up to 25 times.

For the products listed above. Warmed and unwarmed products were tested under conditions similar to clinical use.

Final Polish

Polishing Study Underway — Dr. Richard Price

Objectives

To compare the polish of POGO and Magic Mix/Rock Star Polishing systems before and after 24K toothbrush cycles on a variety of composites.

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Retrospective Case Study

3M

featuring BIOCLEAR

In Progress: Retrospective Study at Clark Dental Group (private practice Tacoma, WA) examining 203 Class II composite restorations placed between 2007-2013.

