COLTENE

Fill-Up!

Dual Curing Bulk Composite

Scientific Documentation

RESTORATION

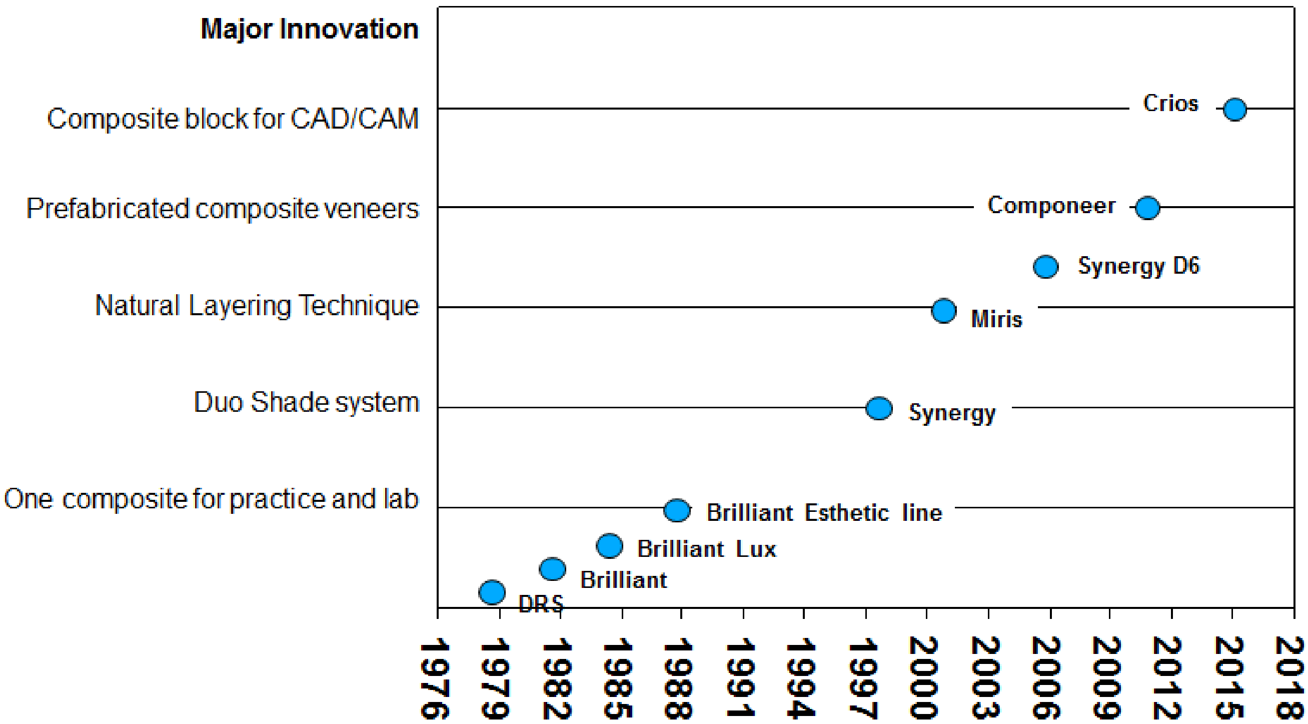
content

1. Introduction

Coltene is a global player in the development, manufacture and sales of consumables for dental treatment applications.

Filling materials, first of all resin matrix composites, are developed and produced since the late 1970ies in Altstätten, Switzerland.

Several successful innovations were introduced by Coltene over the last 3 decades:

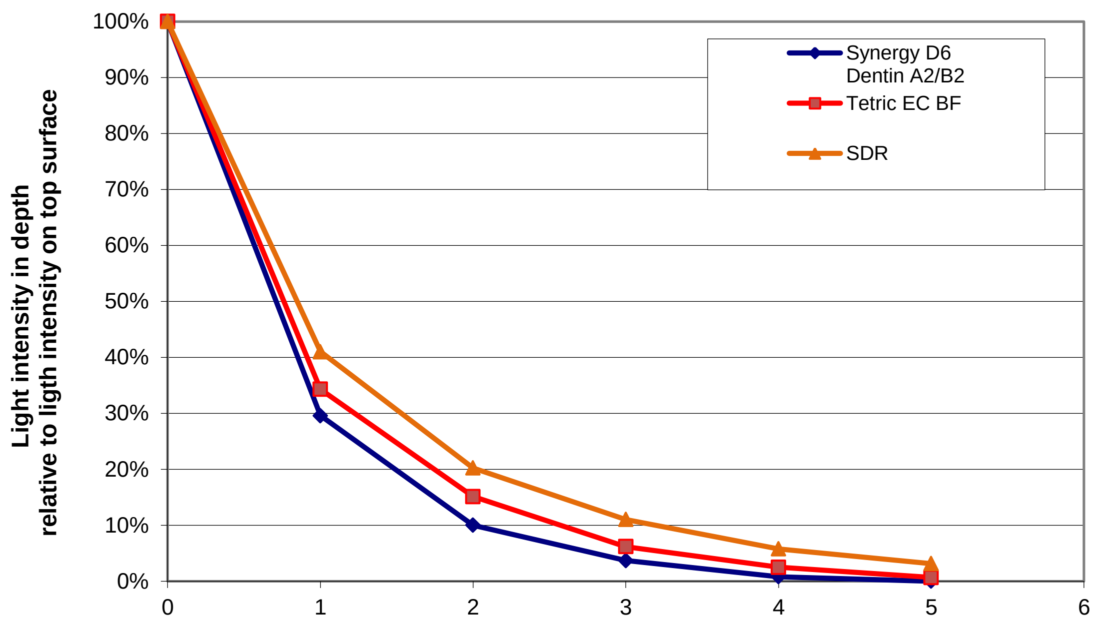


2. Fill-Up!

Coltene had the intention to provide a basic tooth colored filling material that can be applied simply and quickly and results in a functional and robust restoration. The material can be placed as easily as a Glass Ionomer Cement but offers the superior mechanical properties of a composite.

Many competitors have introduced light curing Bulk Fill composites either in flowable or stackable viscosity. Often these composites have a high translucency resulting in a grayish color. Nevertheless the curing depth is limited to 4 or to 5mm. Studies [1,2] have shown that the degree of cure and mechanical properties might be reduced at the bottom of the cavity. This may lead to a reduced mechanical fracture resistance of the restored tooth and /or to a higher risk for sensibilisation due to residual monomers.

The amount of light that penetrates a certain composite depth is decreasing rapidly with increasing layer thickness:



Internal data, Coltene 2013

Only a few percent of the light output reaches a depth of 4 to 5mm in the composite under ideal lab conditions. Is this sufficient in real life? And as can be seen there is not a big difference between a conventional composite and a purpose formulated Bulk Fill material.

Coltene opted for a safe solution with a **dual curing** mechanism: light curing and self curing.

Fill-Up! is a microhybrid 2-component composite consisting of a base and a catalyst paste. The 2 components are mixed during extrusion in a static mixer and the curing starts with a defined delay after the components are brought together. The material can be placed in one layer with unlimited thickness, this means no layering technique is needed. The material properties even allow the use on the tooth surface and in chewing load bearing positions as is proven further down. This makes Fill-Up! a true Amalgam replacement.

Fill-Up! is offered in a universal dentin shade in the range of Vita A2-A3. For cases with higher esthetical requirements a top layer of a universal composite may be added.

3. Technical Data

criteria	unit	method	value*
filler content by weight	w-%	formulation	65
filler content by volume	vol-%	formulation	49
Range of inorganic filler size	µm	formulation	0.1 - 5.0
density	g/cm^3	ISO17304:2013	1.9
Bench work time @ 23°C	s	ISO 4049:2009	189
Setting Time @ 37°C	s	ISO 4049:2009	152
Flexural modulus **	MPa	ISO 4049:2009	7500
Flexural strength**	MPa	ISO 4049:2009	115
compressive strength	MPa	Internal, PA121	289
Vickers hardness	kg/mm2	Internal, FEV002	51
Wear rate McCabe		Internal, FEV 003	2.98
Gloss retention after toothbrush abrasion	GU	Internal, FEV 122/015	51
water sorption	$\mu g/mm^3$	ISO 4049:2009	19
water solubility	$\mu g/mm^3$	ISO 4049:2009	<1
Polymerisation shrinkage Watts	%	Internal, FEV 113	3.3
Viscosity initial	Pa s	Internal, PA 314	319
radio opacity	mmAl	ISO 4049:2009	2.0
Color stability UV Delta E		Internal, FEV 50	2.9

Internal data

*) Typical values based on several measurements

**) same for self curing and dual curing

4. Degree of cure and mechanical properties as a function of cavity depth

External in vitro study by J. Leprince, Université Catholic Louvain la Neuve, BE

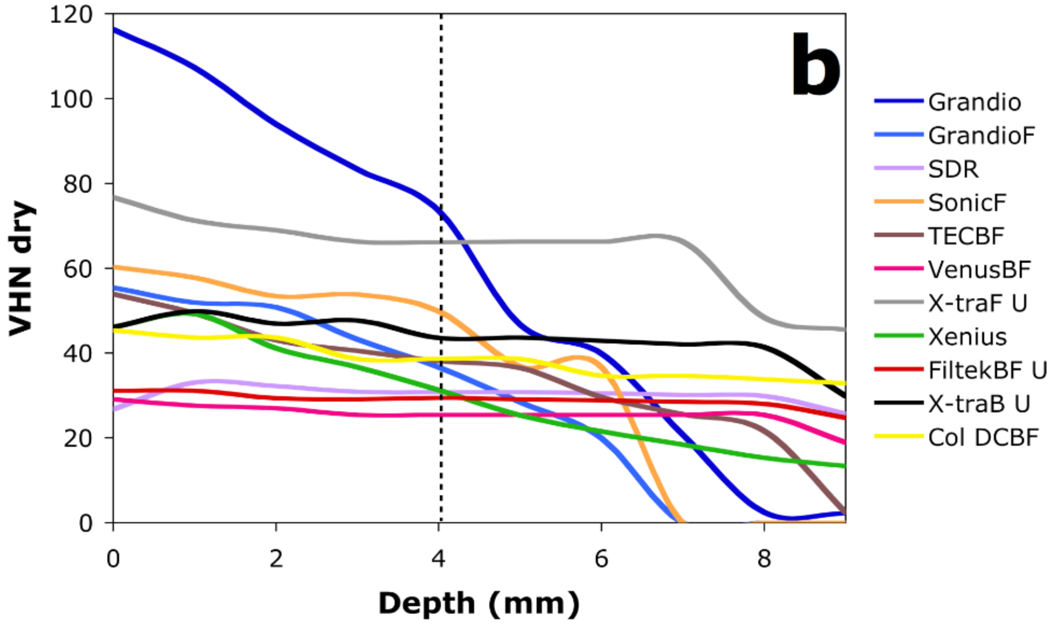
The goal of the study was to compare the degree of curing of various Bulk Fill composites in deep cavities.

Method:

Bulk Fill composites were light-cured for 20s in a Teflon mold of 5x5mm aperture and 10mm depth. Vickers Microhardness (VHNdry) were measured at every millimeter along the sample side (n=3) using Vickers micro indentation. VHN measurement was repeated after 24hours ethanol storage (VHNetOH), to evaluate crosslinking density.

Fill-Up! is marked as “Col DCBF” for Coltene DualCure BulkFill. (yellow line)

Results:



Conclusions:

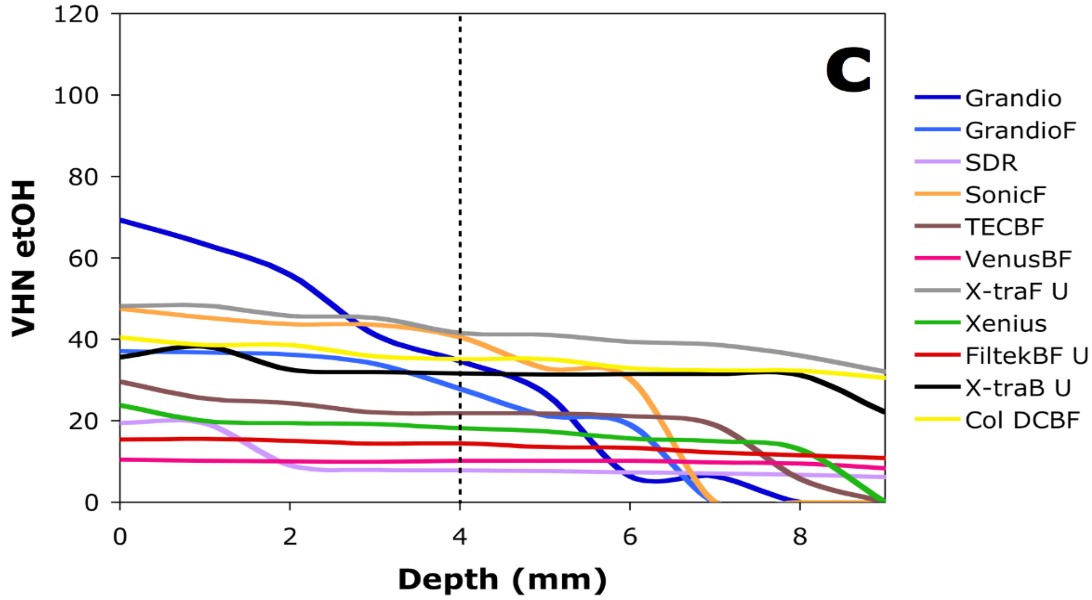
It can be seen that the hardness of Fill-Up! remains on a almost constant level with increasing layer depths.

It may be argued that some light curing competitors show a similar behavior. We attribute this to the study design with a cavity mold made from translucent Teflon in contrast to light blocking stainless steel molds as required by ISO 4049:2009.

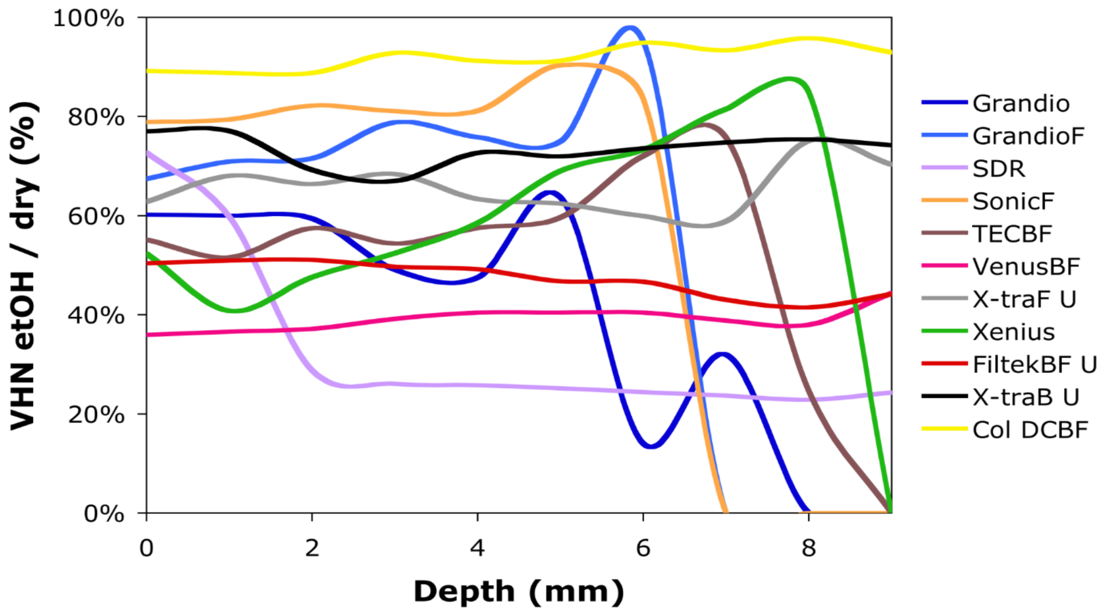
Immersion in a solvent may lead to swelling of a polymer. Ethanol molecules migrate into the acrylic matrix and act as a softener, with other words ethanol may reduce surface hardness. The higher the crosslinking density or degree of curing, the less swelling is observed.

Therefor the extent of hardness reduction after ethanol storage is an indirect measurement of degree of curing.

Results:



Below the results are shown as a combination of the 2 graphs from above.



Conclusions:

Degree of cure of Fill-Up! does not drop significantly with increasing depth.

Degree of cure of Fill-Up! is very high since there is little difference of hardness before and after ethanol storage.

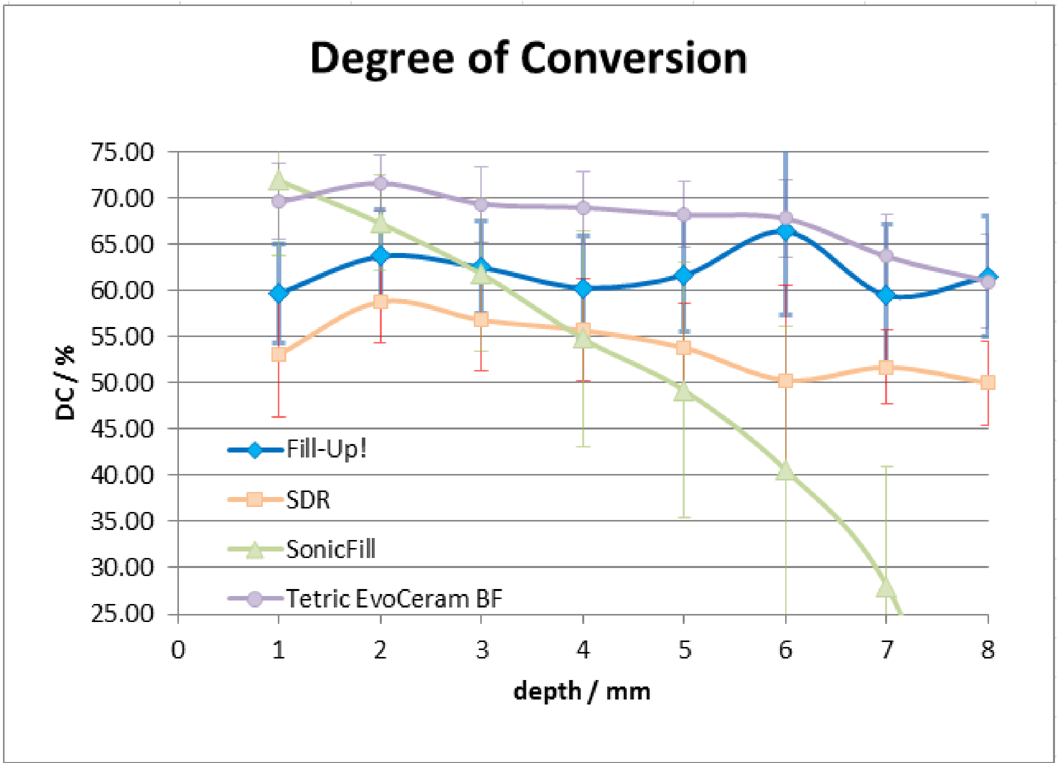
5. Degree of Conversion and Microhardness vs depth

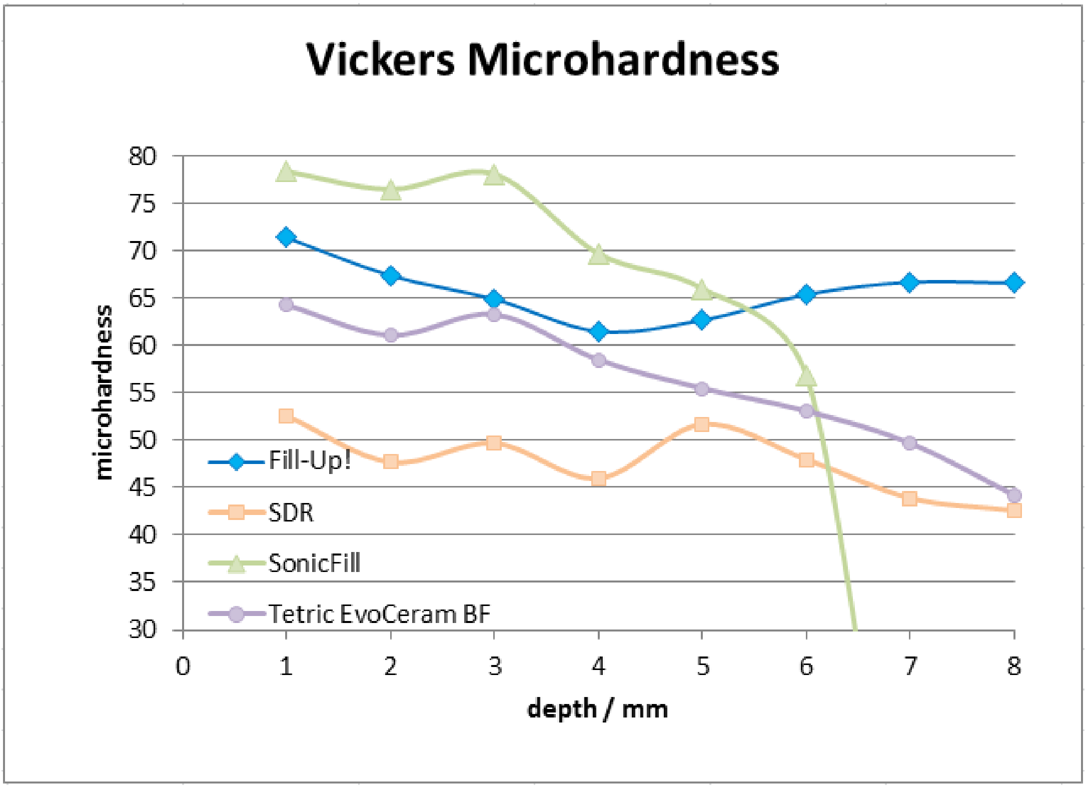
External in vitro study by M. Cadenaro, L. Breschi; University of Trieste, IT
Poster presented at AADR meeting 2018, Fort Lauderdale,US

Method:

A cylindrical mold (height: 8mm; diameter: 5mm) from an opaque polyvinyl-siloxane impression material was positioned on a dentin surface. After application of the adhesive system (ParaBond-Coltene), composites were placed into the mold in bulk and polymerized for 20s with a LED curing light (Coltolux SPEC3) from the top of the cylinder. After 24h molds were removed and composite cylinders were sectioned perpendicular to the top surface. Micro-Raman spectra of the specimens were collected using a Raman equipment (Renishaw InVia) at 1mm intervals from the cavity bottom to the composite surface. Micro-Raman spectra of the uncured and cured composites were collected to identify reference and reaction peaks [605cm^{-1} (C-O-O); 1610cm^{-1} (aromatic ring); 1640cm^{-1} (C=C) group]. DC% was calculated using the ratio between reactive and internal reference peak intensities. VMH assessment was measured on the same specimens at 1mm with a Vickers microhardness tester (Leica Microsystem) at a 200g load for 10s.

Results:





Sonic fill could not be polymerized beyond 6mm. The hardness of SDR was considerably lower compared to the other materials tested.

Fill-Up! was the only material showing a uniform degree of conversion and a uniform microhardness at all depths.

Conclusion:

For Fill-Up! the quality of curing is independent from cavity depth.

6. Knoop Hardness vs depth

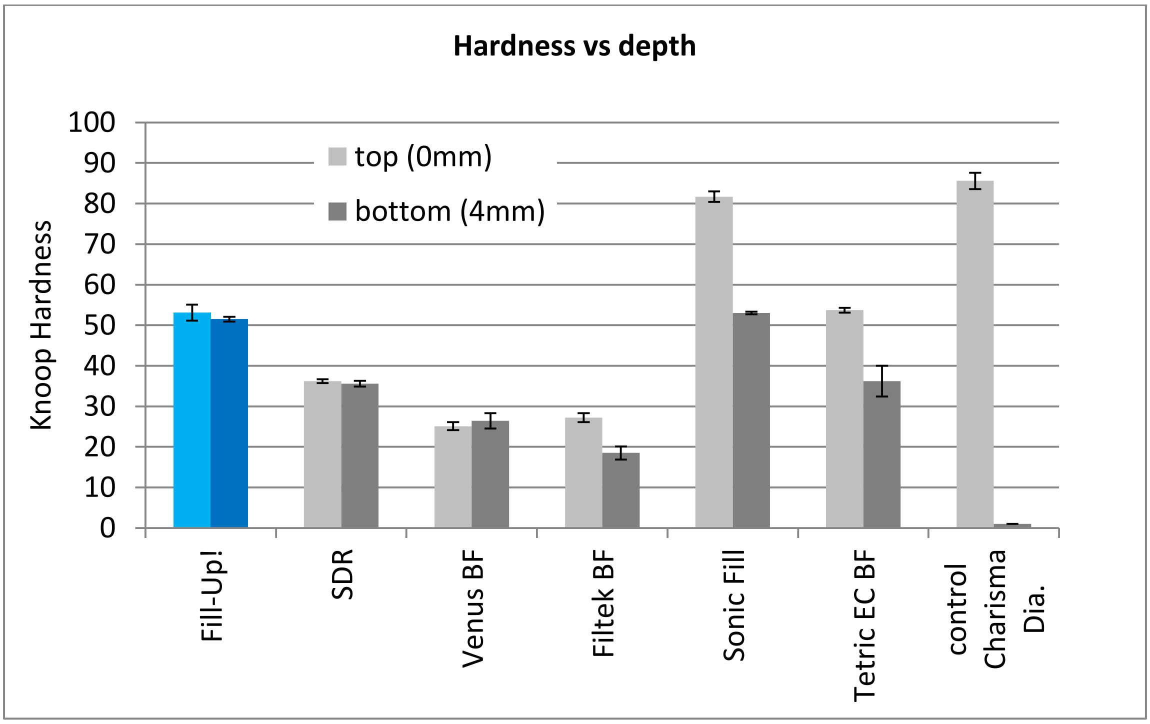
External in vitro study by Rodrigues, Francci; University of Sao Paolo, BR

Method:

Cuboid samples were pressed in metal split molds (height 4mm) and cured 20s with 1000mW/cm2 (Valo cordless). Top and bottom surfaces where polished (1200 grit Buehler) and tested on Knoop hardness (Shimadzu HVM-2).

Results:

Allthough Sonic Fill has highest hardness of all BF composites on top, on the bottom its hardness is the same as for Fill-Up on the bottom. SDR, Venus BF and Fill-Up have the same hardness on top and bottom but Fill-Up has a considerably higher hardness than the other two.



Conclusions:

The hardness of Fill-Up! is the same on top and bottom thanks to its dual curing properties.

The hardness of Fill-Up in 4mm depth is higher than that of the flowable light curing BF composites, it is on the same level as of Sonic Fill and better than Tetric EC BF.

7. Flexural strength vs depth

External in vitro study by: J.Leprince, Université Catholic de Louvain, BE

Goal was to measure flexural strength as a function of cavity depth for various Bulk Fill composites.

Method:

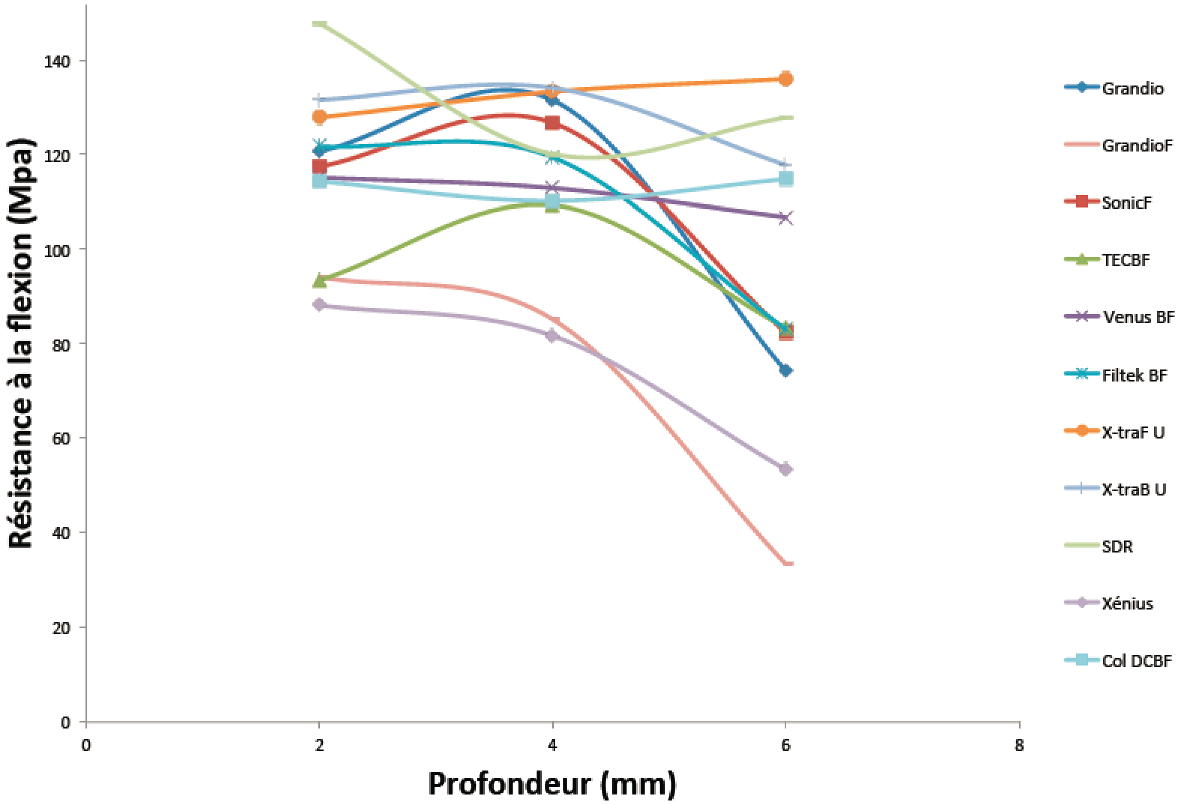
3 purpose designed molds for tensile bars were stacked upon each other, filled with a composite and cured at once from the top surface:

bar 1: 0 - 2mm depth

bar 2: 2 - 4mm depth

bar 3: 4 - 6mm depth

Fill-Up! is marked as" Col DCBF" (Coltene DualCure Bulk Fill)



Conclusions:

The flexural strength of Fill-Up! is not affected by cavity depth. Flexural strength is average in shallow cavities but among the 4 best in deep cavities.

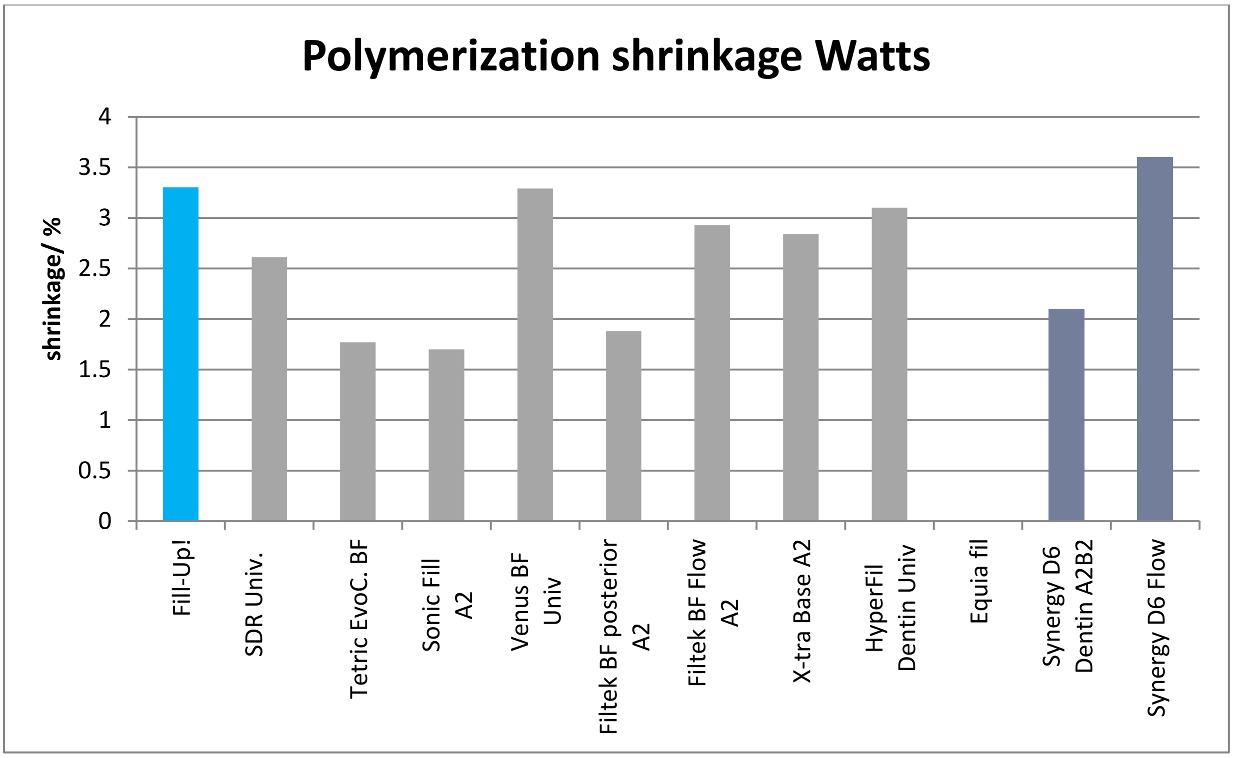
8. Shrinkage

Fill-Up! is a dual curing composite consisting of the two components catalyst paste and base paste. The two components are mixed in a static mixer mounted onto a double barrel syringe. Therefore the viscosity needs to be reasonably low to allow for a manual extrusion through the mixer. Since viscosity increases with the amount of filler the filler loading must be kept on a rather low level and reduced filler load means somewhat higher volumetric shrinkage.

Method:

Polymerization shrinkage was determined according to a method described my Watts (Coltene procedure FEV113)

Results:



Conclusions:

Polymerization shrinkage is rather high as expected but still on a level typical for flowable composites.

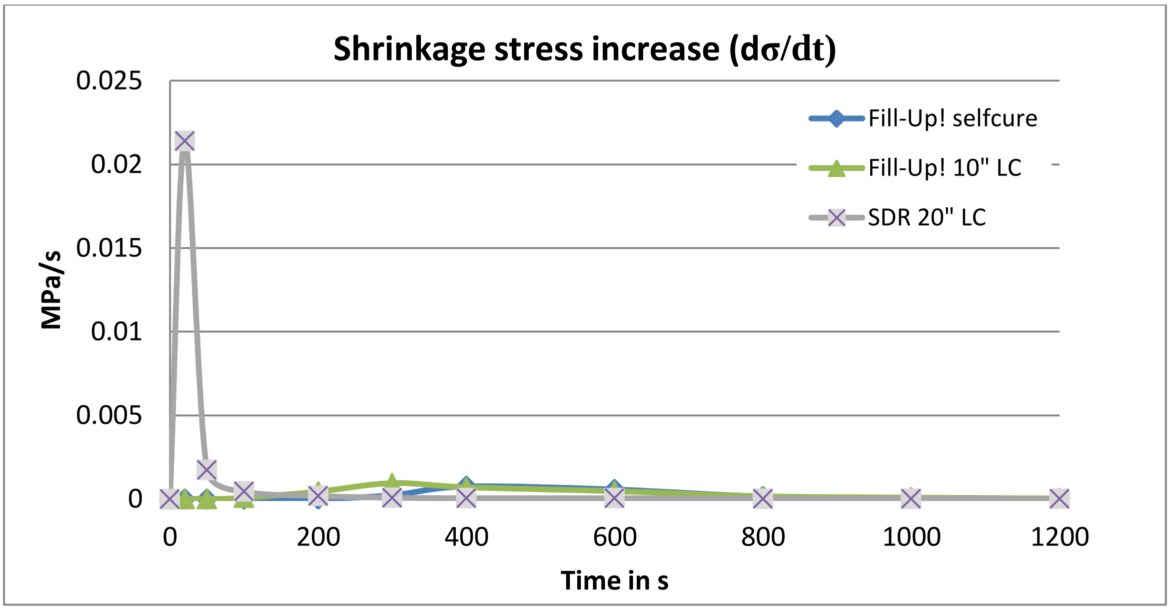
When a restoration material shrinks in a cavity during polymerization shrinkage stresses develop. Shrinkage stress depends not only on volumetric shrinkage but on several other factors such as elastic modulus, irradiance, degree of cure, curing kinetics, geometrical constrains (C – ratio)) and measuring method just to name the most important ones. As long as the shrinkage stress does not exceed the adhesion at the cavity wall we have a restoration with continuous margins, with other words no gap, no leakage. This means that shrinkage stress is clinically more relevant than volumetric shrinkage.

9. Shrinkage Stress

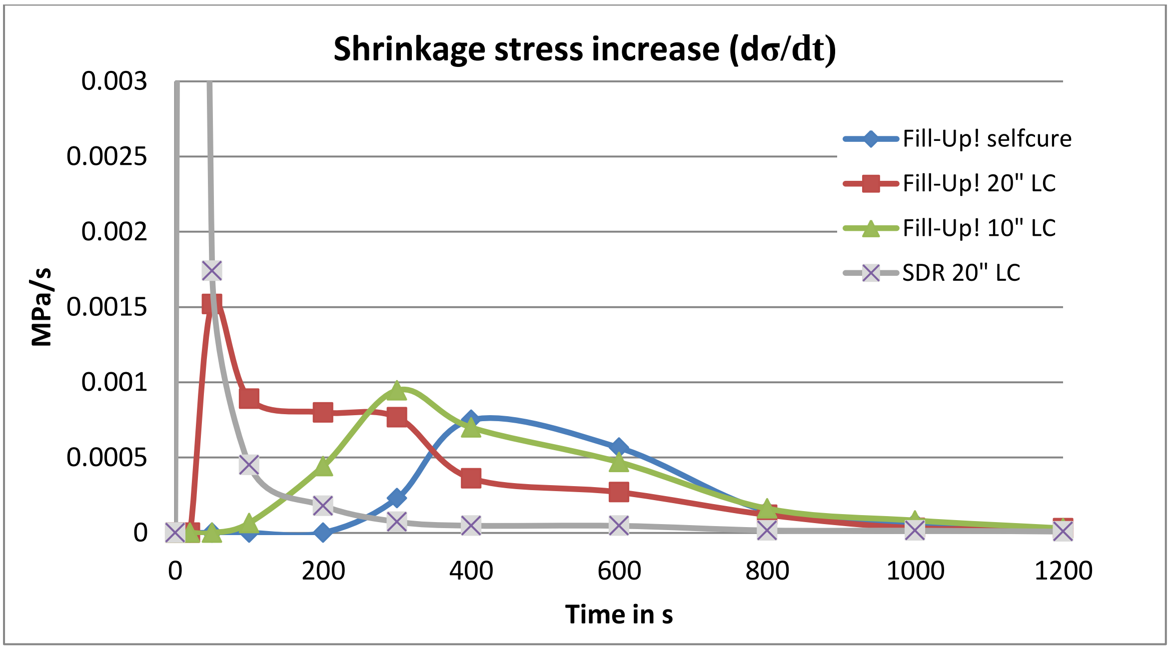
Method:

Shrinkage stress was measured with the tensile testing machine (Coltene method FEV102) for 20 minutes from the beginning of curing.

Results:



Same graph stretched in Y-axis for better differentiation:



Conclusions:

It can be seen clearly that self curing materials have a much gentler development of shrinkage stress because self polymerization is much slower compared to polymerization activated by light. This slower kinetics allow for a shrinkage stress relaxation - at least to some extent - until the freedom of movement of the growing macromolecules is inhibited by crosslinking. The diagram also makes clear why Coltene recommends only 10” light curing for stress reduction purposes.

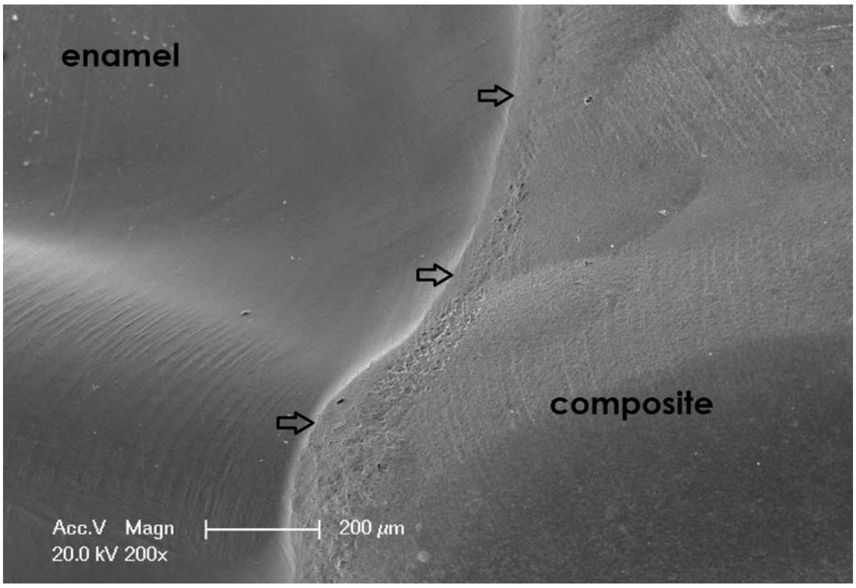
10.Marginal Adaptation after Chewing Simulation

External in vitro study by I. Krejci, University of Geneva

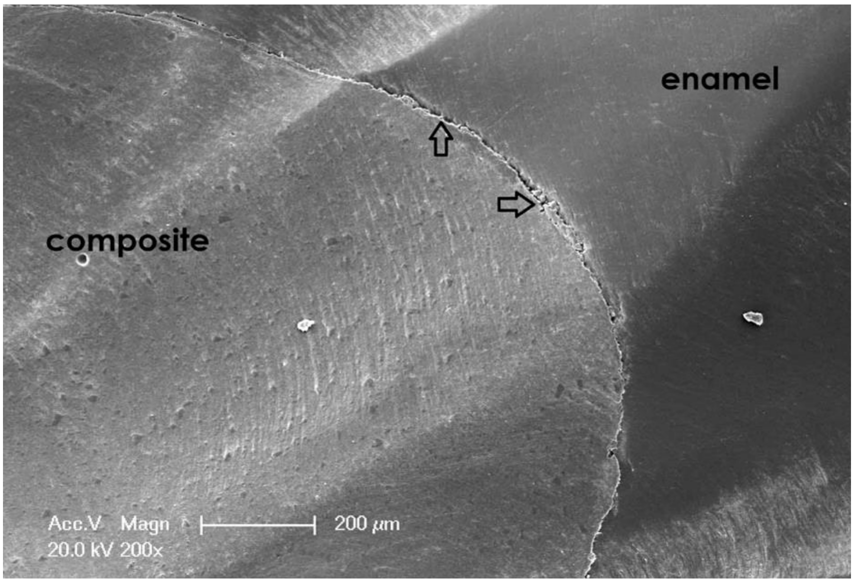
Method:

Standardized class II MO cavities were prepared in extracted human molars. The teeth were restored with two horizontal increments of composite. The first increment was filled in bulk with 4mm thickness, the second increment with 2mm as top layer. As a second option Fill-Up was applied in a single layer with 6mm thickness. After finishing procedures, impressions were made using a polyvinyl siloxane and epoxy resin replicas were obtained. Thermo-mechanical stressing was carried out 24 h after the restorative procedure. All specimens were submitted to 240,000 occlusal loading and simultaneous 600 thermal cycles in water at 5 8C and 50 8C. After loading, a new set of epoxy resin replicas was obtained. Scanning electron microscopy was carried out at 200x magnification. Results for the marginal adaptation were expressed as percentages of continuity relative to the exposed interface.

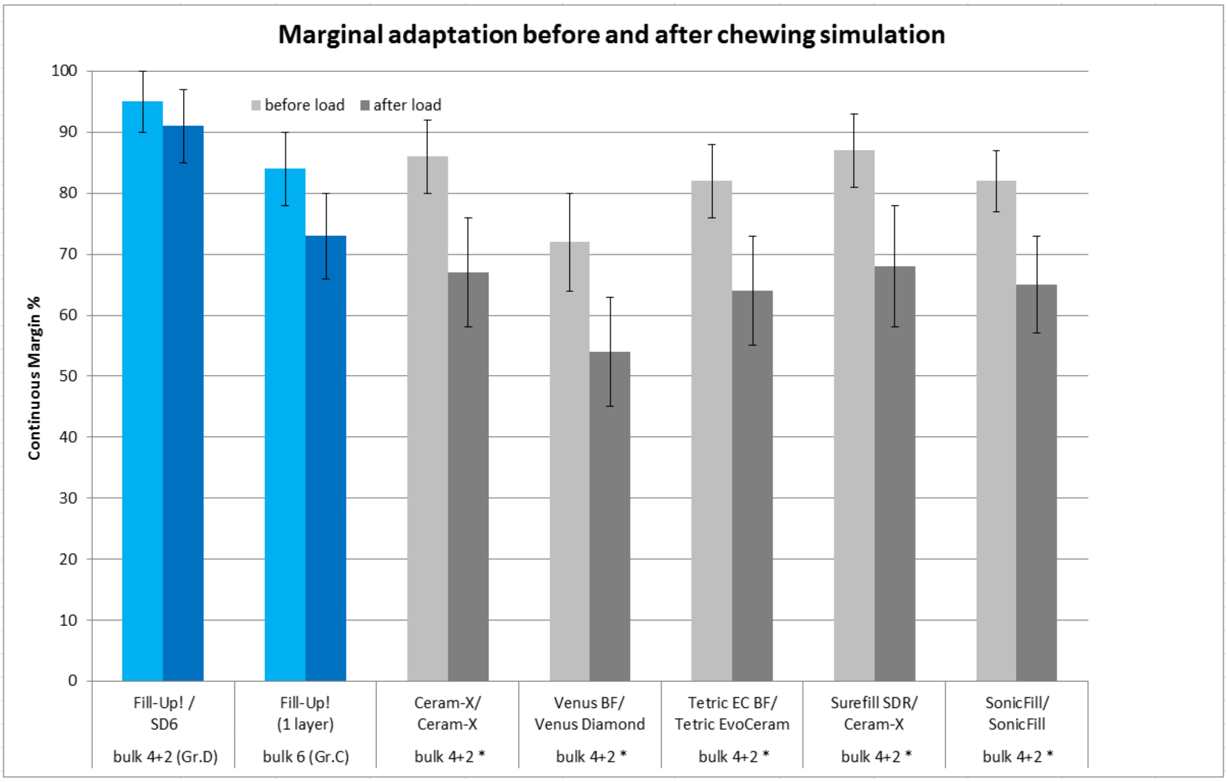
Results:



example of continuous margin in enamel at the occlusal surface



example of non-continuous margin in enamel at the occlusal surface



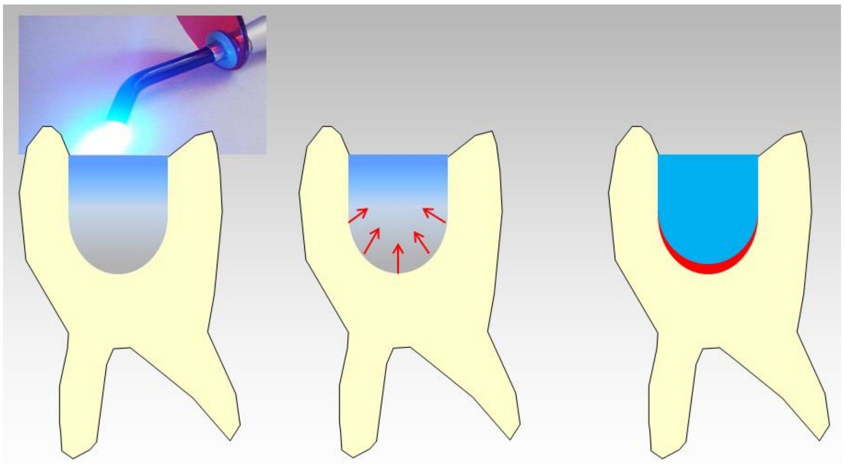
Conclusions:

The restoration with Fill-Up! shows the most perfect margins, after placement and after stressing, when placed with a top layer of Synergy D6. Even with the simplified true bulk fill procedure of one layer without an additional top layer the marginal adaptation after chewing simulation is at least as good as with light curing competitor bulk fill composites placed with an additional top layer.

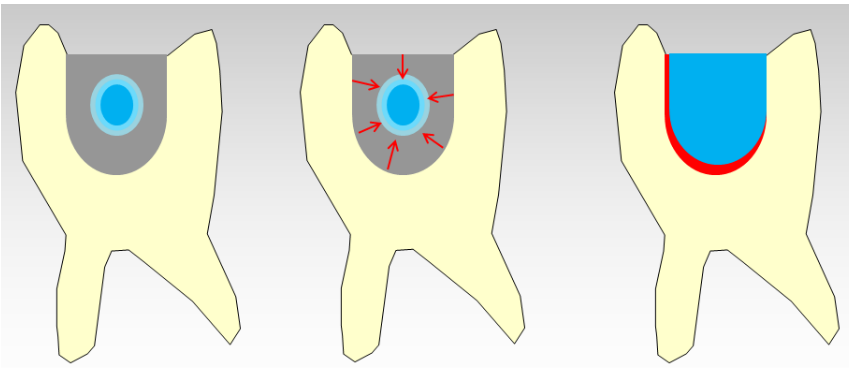
11. Bondings

To achieve the good marginal adaptation as presented above it is crucial to use a fitting bonding system. Ideal is a bonding that catalyzes the curing of the dual curing filling composite. Why this?

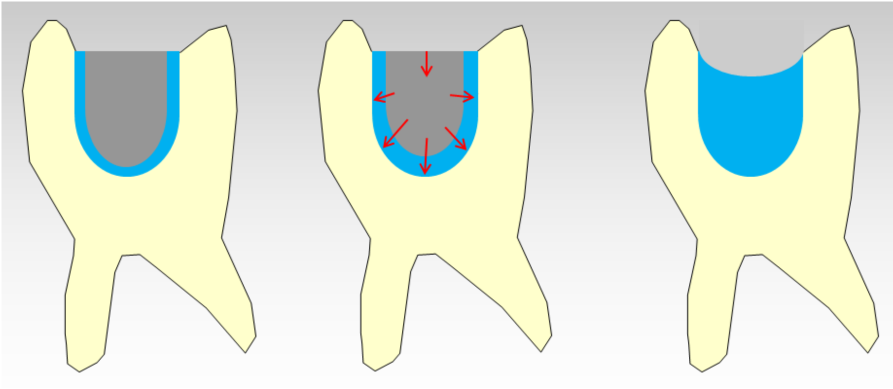
Light curing composites start curing from the surface where the light is coming in, simply because there is the highest light intensity creating the highest initiator radical concentration. This means a rigid surface skin is created and the composite shrinks towards the incoming light and away from the cavity floor:



Self curing composites initially start curing homogeneously all over. Since curing is an exothermal reaction the temperature in the composite raises leading to a self acceleration of the curing reaction. Because of heat dissipation temperature rises the most in the center of the bulk portion an as a consequence the composite solidifies from inside out. The shrinkage vector points towards the center of the composite portion:



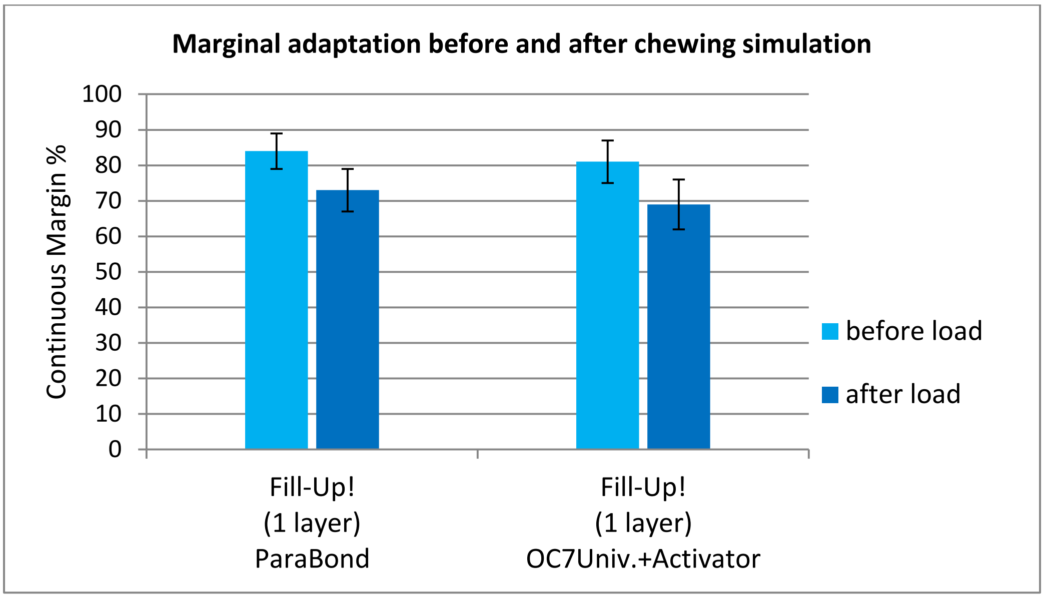
When there is catalysis of curing by the adhesive the composite solidifies first along the cavity walls leading to very stable interface. The composite shrinks towards the margins creating a sink in the occlusal surface that does not disturb. This is by far the most tolerable way of shrinking.



This effect is preferably achieved with the Coltene ParaBond system. Over many years ParaBond is successfully used in combination with Coltene's Dual Curing Composite ParaCore. Studies[3] have proven a very good sealing of restorations.

The same mechanism takes place using a light curing Universal adhesive when a compatible activator is added. This has been verified by using the bonding system OneCoat 7 Universal together with OneCoat 7.0 Activator.

Krejci, University of Geneva found a marginal adaptation after chewing simulation comparable to restorations with the proven bonding system ParaBond. (Method see p.12)

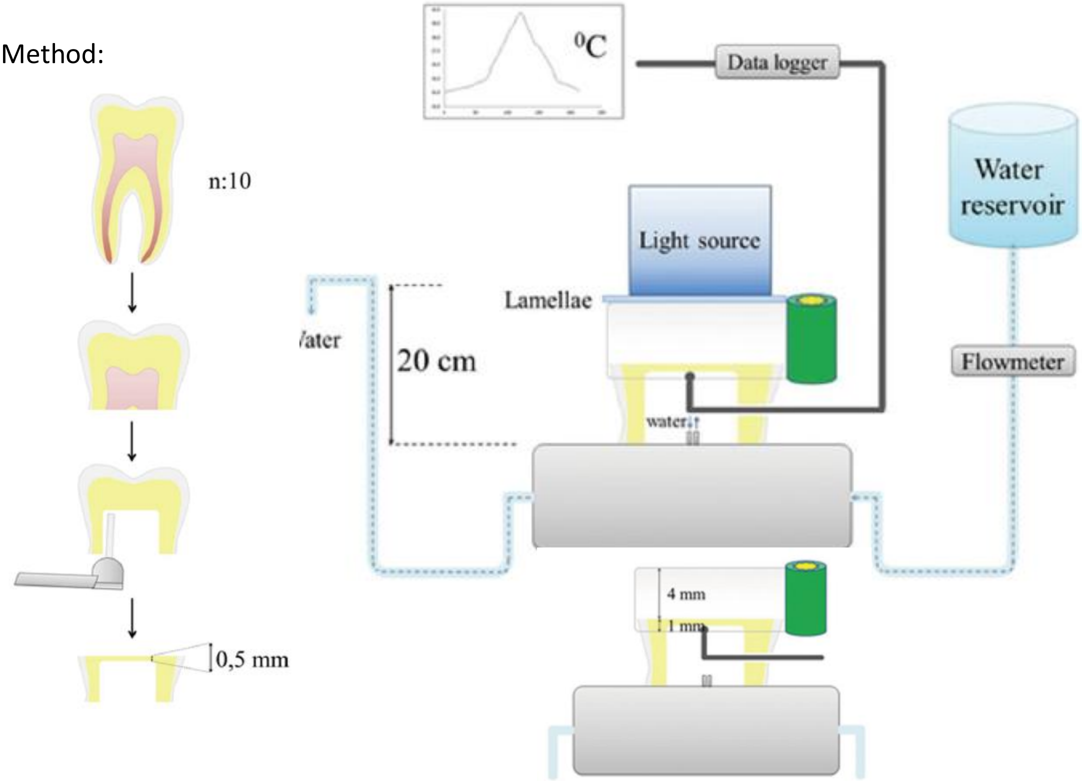


12. Heat stress on pulp

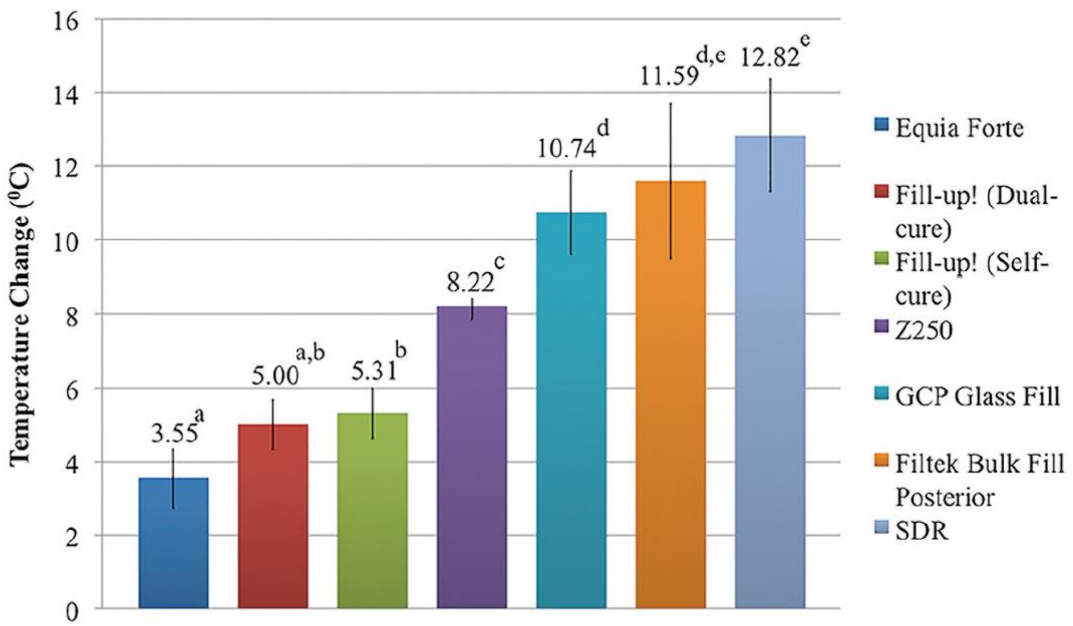
External in vitro study by Yasa, Izmir TR, DOI:10.4012/dmj.2016-200 https://www.ncbi.nlm.nih.gov/pubmed/28626204

Aim:
Investigation of intrapulpal temperature changes during curing of different bulk-fill restorative materials.

Method:



Results:
Critical Temperatures for irreversible damage to the pulp begin at 42 -42.5°C (Pohto and Scheinin) depending also on duration of exposure. This corresponds to a temperature rise of approx. 5.5°C. For light curing materials higher temperature changes than this critical value have been measured, but not so for Fill-Up!



Self- and Dual curing materials might have a lower risk to cause pulpal damage during curing.

13.Polish

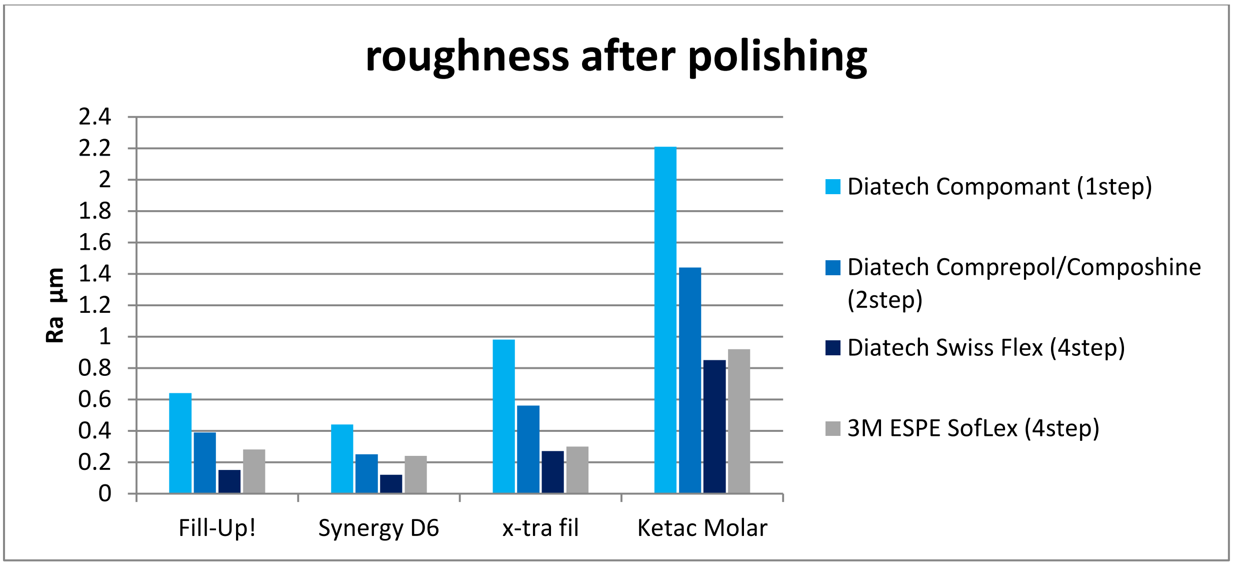
External in vitro study by S.Flury, University of Bern.

In section 9 it has been shown that Fill-Up! can be placed as a true Bulk Fill or Amalgam replacement with excellent marginal adaptation by filling a cavity in one increment. But what are the esthetic properties of Fill-Up! when used without cover? The goal was to investigate polish quality of Fill-Up!

Method:
Cylindical samples have been prepared in custom-made acrylic resin molds with circular cavities (Ø4 mm). The molds were filled with one of the restorative materials investigated.
The restorative materials have been cured according to their IFU. For light curing a LED curing light Coltene SPEC3, 11mm light guide, 1600mW/cm2 has been used.
Immediately after curing the samples have been sanded according to a standardized procedure and polished with one of the following systems, according to their IFU:

- Diatech Compomant Plus, 1-step
- Diatech Comprepol Plus / Composhine Plus, 2-step
- Diatech SwissFlex, 4-step
- 3M ESPE SofLex, 4-step

Results:



Conclusions:

As expected the 4step polishing systems Diatech SwissFlex and 3M ESPE SofLex deliver the lowest surface roughness. But the 2 step Diatech Comprepol Plus / Composhine Plus comes close to the 4 step system especially when used on Coltene composites.

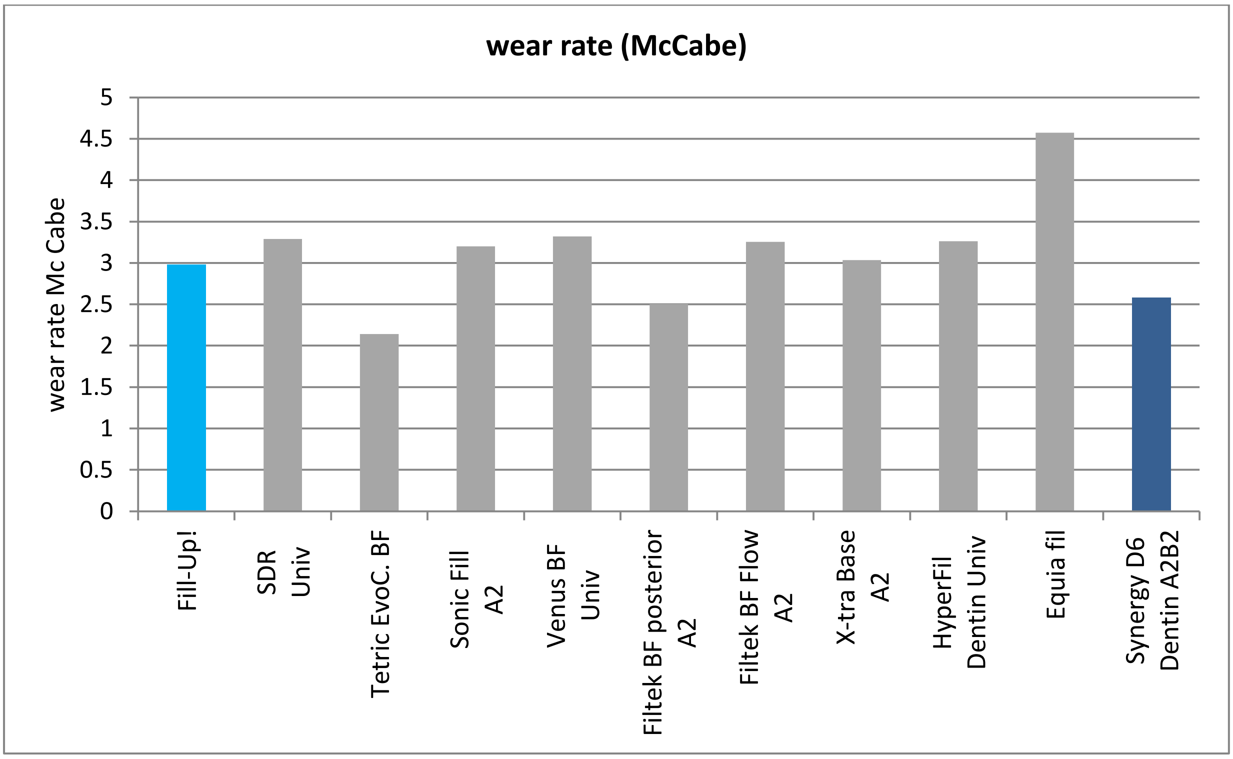
Independent of polishing procedure the ranking of the composites remains the same. Fill-Up! can be polished to almost the same low roughness as Coltene's proven Universal composite Synergy D6. Therefor Fill-Up! is suitable to be used at the surface of a restauration regarding polish or gloss.

14. Wear resistance

Method:

To assess the material loss by abrasion a method described by McCabe was applied. Composite is pressed into cylinders Ø5mm, h: 6.7mm, and light cured for 60s from each side plus 90s in the light furnace, cylinders are stored in DI water at 37°C for 7days. A cylinder is placed in an abrasive paper (SiC P800) coated vial and agitated by a flask shaker with 800osc/min for 480min. Weight loss is measured and wear rate relative to an Amalgam Standard is calculated. (Coltene method FEV003)

Results:



Conclusions:

Some stackable highly filled competition composites show less wear as expected, but the wear resistance of Fill-Up! is on a acceptable level and in the same range as SonicFill that is indicated for use on tooth surfaces.

The Glass ionomer restorative Equia Fil shows the highest abrasion by far.

15. Antibacterial properties

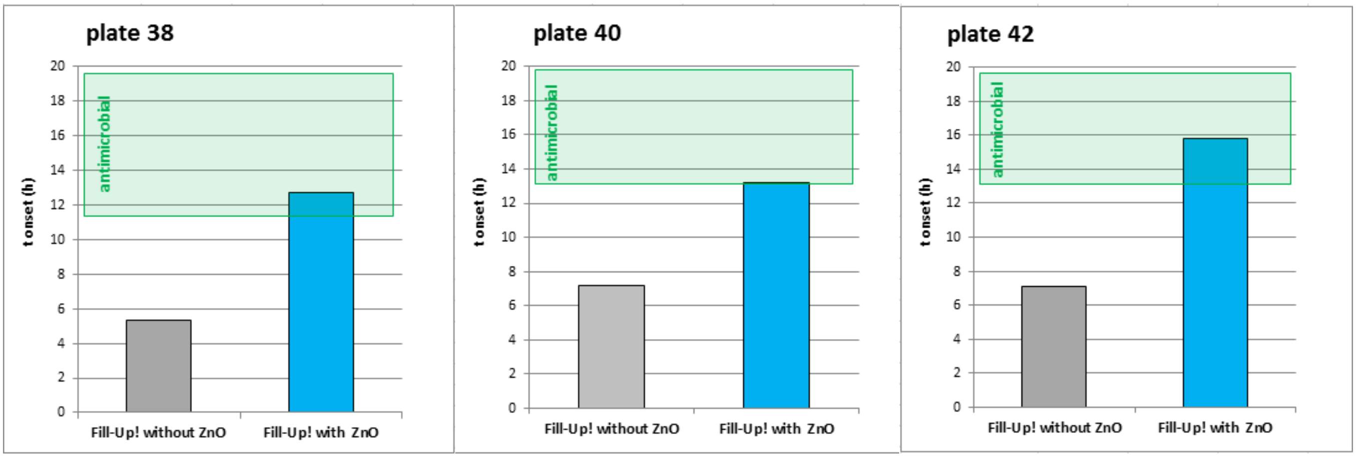
External in vitro study by Quality Labs BT GmbH, Nürnberg*

The goal was to assess if the addition of zinc oxide in the formulation of Fill-Up! has an effect on bacteria growth on the composite surface.

Method:

The tests were conducted according to Quality Labs SOP3.2 from 2008-08-05 „Assay zur Bestimmung antimikrobieller Wirksamkeit von Werkstoffoberflächen gegen *Staphylococcus epidermidis DSM 18857“.* Cylindrical cured composite specimens were incubated with cells of the testing stem. Non adhering cell material was washed off. The composite was challenged to inhibit the proliferation of the bacteria on its surface over a period of 18h at 37°C. If the inhibition was not complete, living daughter cells were released to the testing medium. The testing medium was cultivated and observed over 48h and the onset of a critical perturbation in the medium was recorded. The higher the antimicrobial efficiency of the composite the longer the onset time was delayed. A material causing a delay of >6h over a relevant control specimen is defined to be antimicrobial.

Results:



Conclusions:

Three series (plates) were tested. All three showed a significant delay of the onset time over the negative control. According to the definition all series proved antimicrobial properties of Fill-Up!

*) Quality Labs BT GmbH is certified by:

- DAkkS, Deutsche Akkreditierungsstelle D-PL-13335-01-00
- ZLG, Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten, ZLG-AP-231.10.72

16.Durability of Chemical Cured Composites placed in bulk

Clinical study by U. Pallesen, University of Copenhagen DK and J.van Dijken, Umea University, SE
http://dx.doi.org/10.1016/j.dental.2015.08.146

Method:
30 years follow up of a randomized controlled study.
30 participants , each of them received a set of 3 Class II restorations with 3 different composites:

- Miradapt, Johnson & Johnson, Chemical curing 2 paste Hybrid Composite
- P10, 3M Dental Products, Chemical curing 2 paste Hybrid Composite
- P30, 3M Dental Products, light curing Hybrid Composite

The chemical curing materials were placed in bulk, the light curing material in 2mm increments.

Results:
5 participants dropped out over the 30 years.
The survival probability after 30 years was found to be:
74% for Miradapt
69% for P10
59% for P30

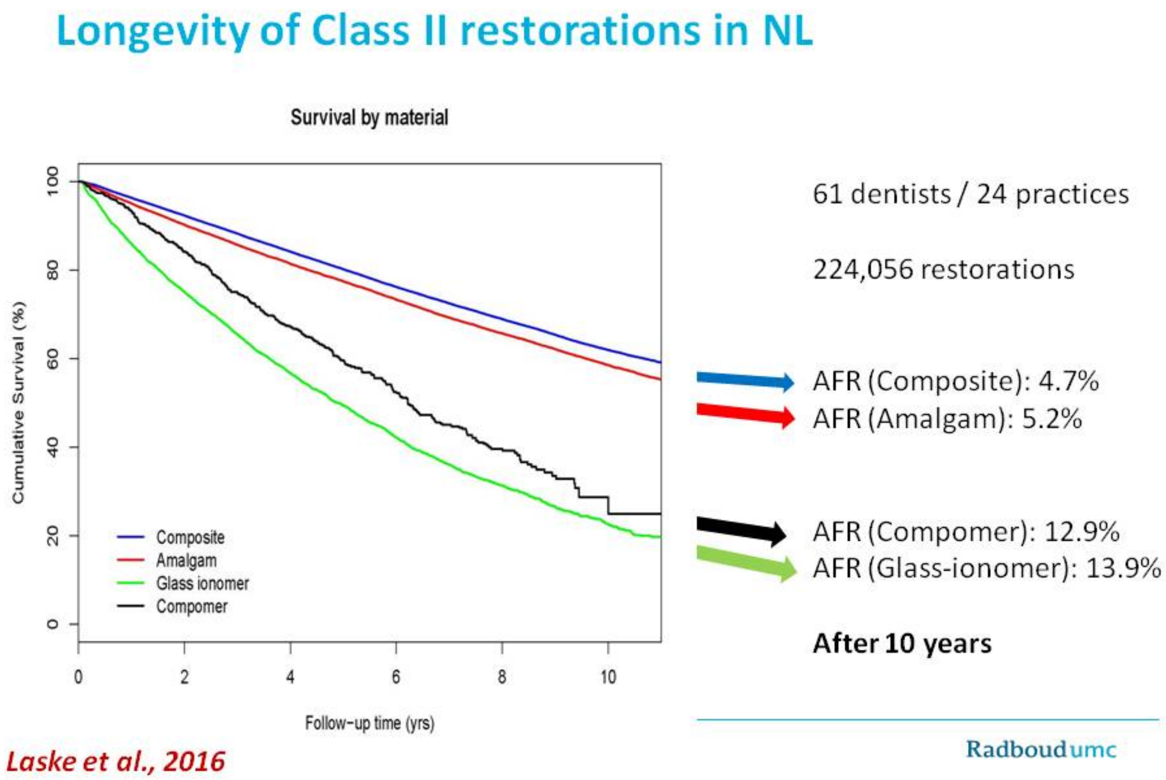
The average survival probability for the 2 chemical curing resins is 72% after 30 years.
This means out of 100 restorations only one was lost every year.

Conclusions:
The chemical cured resin composite restorations placed in bulk showed a lower failure rate than the light cured material.

Although this amazing study was not done with the dual curing composite Fill-Up! it shows that chemical curing works as good as light curing.
Bulk placement of chemical curing composites is nothing really new and works as good as layering with light curing composites.

17. Durability of Composites vs Glass Ionomers

Results from practice based network by Laske, Radboud University NL, slide presented by N. Opdam at IADR General session 2017:



Conclusion:

This study was not done with the dual curing composite Fill-Up!

It shows that

- with composites a durability similar to Amalgam can be reached in a general practice.
- the durability of composite restorations is significantly higher compared to glass ionomer.

References

1.) J. Leprince, New insight into depth of cure of dimethacrylate-based dental composites, Dental Materials 28 (2012) p.512-520
2.) G. Cristensen, Do the Benefits of Bulk Filling outweigh the challenges, Clinicians Report Vol 7 - 10 (2014)
3.) B. Millar, Comparing Total-Etch with Bonding Resin and Self-Etch Adhesive Luting Cements for All-Ceramic Crowns, Open Journal of Stomatology, 2014, 4, p.126-134

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