Scientific Documentation

ivoclar vivadent
passion vision innovation

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1. Introduction

1.1 *Direct composites*

Dental composites have developed hand in hand with dental adhesives. Composite materials became available in dentistry in the 1960s, [1] and initially they were mainly used in the anterior region, where amalgam fillings were deemed unaesthetic. In the 1990s they began to substitute amalgam as a universal filling material and composite restorations heralded a new minimally invasive era in dentistry. The retentive aspect of amalgam fillings was no longer necessary as the hole to be filled, had only to be as large as the demineralised tissue to be removed. This new development in restorative dentistry was only possible due to the simultaneous development of clinically reliable enamel/dentin adhesives.

The composite success story was driven, not only by patient demand for increasingly aesthetic universal filling materials but by continued industry-led product development and improvement with regard to the physical, aesthetic and handling qualities of adhesives and composites.

1.1.1 A short history

As the name suggests, composites are comprised of at least two different materials. In most cases this involves inorganic or organic fillers which are embedded in an organic matrix. The first step in the development of composite materials was achieved by Bowen in 1962 with the synthesis of a Bis-GMA monomer-formulation filled with finely ground quartz. [1] At the time, only chemically-cured two-component resin-based materials were available. With the advent of photo-polymerisation, UV-cured systems were introduced [2] and in the late 1970s, the first report on a dental filling material that could be cured with visible blue light was published. [3] Direct composites were historically somewhat limited with regard to large posterior restorations due to accelerated wear and polymerisation shrinkage issues. Thus in the 1980s the first generation of indirect (lab-based) composites was introduced. These were/are modelled and cured extra-orally in units capable of delivering higher intensities of light/heat than would be possible intra-orally. The bulk-fill type of direct composites specifically designed for large posterior restorations represent a new era in direct filling technology and a paradigm shift away from the traditional 2 mm increment system.

1.1.2 Composite monomer technology

Monomers, together with the initiators, catalysts and other additives form the reactive part of a dental composite restorative. The monomers compose the matrix of a composite material. They must be stable in the oral environment, exhibit shade stability and low polymerisation shrinkage (high molecular weight). High molecular, multi-functional (mostly bi-functional) methacrylate compounds have proven most suitable for this purpose.

Bis-GMA (bisphenol-A-diglycidyl-dimethacrylate) was first synthesised and introduced in the early sixties and is one of the most frequently used monomers. Due to a propensity for water absorption, which can lead to swelling and discoloration, it tends to be used in relatively small amounts and mixed with other methacrylates. Most resin matrices consist of dimethacrylate mixtures. Dimethacrylate refers to methacrylates with two polymerisable methacrylate groups. UDMA (urethane dimethacrylate) is another common compound, and has the advantage of having a lower viscosity than Bis-GMA. It can therefore be used undiluted and as UDMA has no hydroxyl side groups (OH groups), it exhibits low water absorption. Modern composite materials usually consist of low viscous dimethacrylates in combination with Bis-GMA.[4] The overall monomer content of a composite, accounts for approximately 12 - 40% of the mass, depending on the characteristics of the product.

1.1.3 *Composite filler technology*

Fillers are responsible for imparting composites with the adequate strength to withstand the strains and stresses of the oral cavity and to achieve acceptable clinical longevity. Composite restoratives tend to be classified according to their filler composition i.e. macrofilled, microfilled or hybrid composites. Macrofilled composites predominantly contain glass fillers with a mean particle size of >3 µm. Microfilled composites mainly contain filler particles with a mean diameter of less than 100 nm and today such fillers are called nanofillers. In hybrid composites, the spaces between the coarse filler particles, which usually have a diameter of less than 1 µm, are occupied by microfillers. Fillers in differing types, sizes and concentrations determine the translucency, strength, opalescence and radiopacity of a material and are crucial for reducing wear and polymerisation shrinkage as their inclusion enables the reduction of the monomer content.

Macrofillers

The first composites contained just macrofillers. These macrofilled composites exhibited favourable shrinkage behaviour and flexural modulus, but their surface properties were inadequate and their wear properties poor. In essence, they were clinically unsuccessful. [5]

Microfillers

In 1974 a patent was granted to Ivoclar Vivadent for a composite employing microfillers.[6] Microfilled composites heralded a breakthrough as they were the first materials to be sufficiently wear resistant whilst maintaining good surface quality in the mouth. Microfillers could not however overcome two essential problems: Firstly, they could not reinforce a composite material as effectively as macrofillers, resulting in low flexural strength and low flexural modulus; and secondly microfillers severely increase the viscosity of a composite due to their high specific surface area, meaning only limited amounts can be used. As a result, microfilled composites exhibit high polymerisation shrinkage. This can however be largely overcome by preparing an initial microfilled composite which is then ground to a fine powder and employed as a filler in the final dental material. These organic polymer fillers can be termed “Isofillers”. Ivoclar Vivadent used this filler technology as early as the development of Heliomolar. Microfilled composites typically demonstrate higher wear resistance than other types of composite materials because of the smaller size of the particles.[7]

Hybrid-fillers

Hybrid composites represented the next logical step in composite development. As the term 'hybrid' suggests, a variety of different fillers are employed to optimally combine the properties of all types of fillers, further improving the mechanical properties of the final material. This allows for a very high filler load, resulting in high physical strength and reduced polymerisation shrinkage. This technology was employed in the creation of the micro-hybrid products Tetric and Tetric Ceram and the nano-hybrids Tetric EvoCeram and Tetric EvoCeram Bulk Fill.

1.1.4 *Bulk fill composites*

Composites with improved depth of cure and reduced shrinkage characteristics for bulk fill purposes have been around for some years. In 2008, Polydorou et al [8] published an in vitro study in which the depth of cure of two translucent composites were evaluated. Independent of the light source (LED or halogen) they showed that adequate curing of QuiXfil/Dentsply samples was possible to a depth of 3.5 to 5.5 mm. Using the same method with micro-filled composites they achieved a depth of cure of just 2.5 mm.

It is important to note that bulk fill materials do not constitute a uniform class of materials. While the ability to apply the material in thick increments is a common theme, there are differences in clinical application and the way in which the fillings are built up. A selection are summarised in the table below:

Product	Manufacturer	Consistency	Increment Thickness	Application
Tetric EvoCeram Bulk Fill	Ivoclar Vivadent	Sculptable	4 mm	Single layer possible
QuiXfil	Dentsply	Sculptable	4mm	Single layer possible
x-tra Fil	Voco	Sculptable	4 mm	Single layer possible
Venus Bulk Fill	Heraeus Kulzer	Flowable	4 mm	Over-layered with conventional composite
SDR	Dentsply	Flowable	4 mm	Over-layered with conventional composite
SonicFill	Kerr	Flowable, sound activated, sculptable	5 mm	Single layer possible
x-tra base	Voco	Flowable	4 mm	Over-layered with conventional composite
Filtek Bulk Fill	3M Espe	Flowable	4 mm	Over-layered with conventional composite

Table 1: Summary characteristics of various bulk fill composites

All bulk fill composites need to exhibit low shrinkage stress and thus marginal integrity, adequate resistance to chewing forces in the posterior region, adequate working time in ambient light, adequate radiopacity, plus good polishing properties and aesthetics.

The sculptable (non-flowable) materials can be applied in one increment and moulded and sculpted to mimic the natural tooth topography. Flowable materials are unsuitable for single layer fillings however as they cannot be sculpted at the surface. They need to be over-layered by a conventional composite in order to model cusps and create life-like morphology.

2. Tetric EvoCeram Bulk Fill

Tetric EvoCeram Bulk Fill takes composite-technology to the next level. Based on the clinically reliable universal composite Tetric EvoCeram, Tetric EvoCeram Bulk Fill is a light-cured, nano-hybrid composite for direct restorations in posterior teeth, and may also be used for class V restorations and extended fissure sealing. Tetric EvoCeram Bulk Fill can be applied in “bulk” increments of up to 4mm, it can be sculpted and may be polymerised in just 10 seconds (light source: >1000 $mWcm^2$) without compromising the material’s physical properties. It can however also be polymerised with conventional LED curing lights. The possibility to cure 4mm increments represents a paradigm shift in dentistry. For years it has been an accepted fact that to create a reliable composite with minimal polymerisation shrinkage the composite had to be applied in layers of not more than 2 mm and each layer had to be individually light cured. To refute this tradition the chemical and physical parameters of composites had to be re-thought.[9] Tetric EvoCeram Bulk Fill involving advanced composite-filler technology, a pre-polymer shrinkage stress reliever, a light initiator/polymerisation booster (Ivocerin®) and a light sensitivity filter represent this re-think.

2.1 Monomer technology

Tetric EvoCeram Bulk Fill contains the same dimethacrylates as Tetric EvoCeram: Bis-GMA, Bis-EMA and UDMA. As with all composites these are converted into a cross-linked polymer matrix during the polymerisation process. The organic matrix of Tetric EvoCeram Bulk Fill accounts for approximately 21% of the mass. Bis-GMA, Bis-EMA and UDMA exhibit low polymerisation shrinkage by volume. Both Tetric EvoCeram and Tetric EvoCeram Bulk Fill are the result of a coordinated optimised mixture of monomer matrix and fillers.

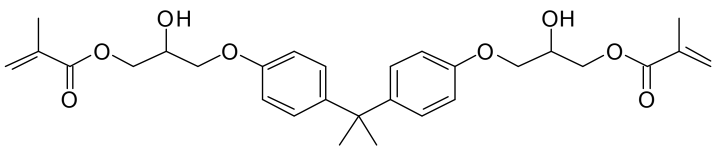
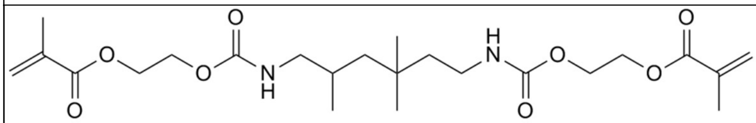
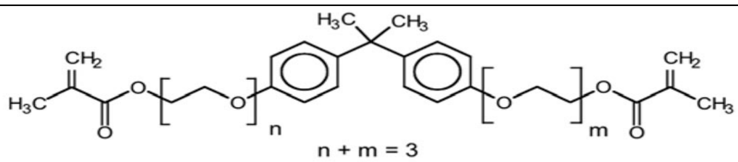
	**Bis-GMA** Bisphenol A-diglycidyl dimethacrylate
	**UDMA** Urethane dimethacrylate
	**Bis-EMA** Ethoxylated bisphenol A dimethacrylate

Table 2: Table illustrating the structural formulae for the monomers used in Tetric EvoCeram Bulk Fill

2.2 *Filler technology*

The filler technology behind Tetric EvoCeram Bulk Fill is also based on that of the clinically proven Tetric EvoCeram. Tetric EvoCeram Bulk Fill incorporates several different types of filler (barium aluminium silicate glass with two different mean particle sizes, an „Isofiller“, ytterbium fluoride and spherical mixed oxide) in order to achieve the desired composite properties. Tetric EvoCeram Bulk Fill has an overall standard filler content of approximately 61% (vol.) and 17% „Isofillers”. Illustrations of the various fillers contained in Tetric EvoCeram Bulk Fill are shown below:

Glass fillers

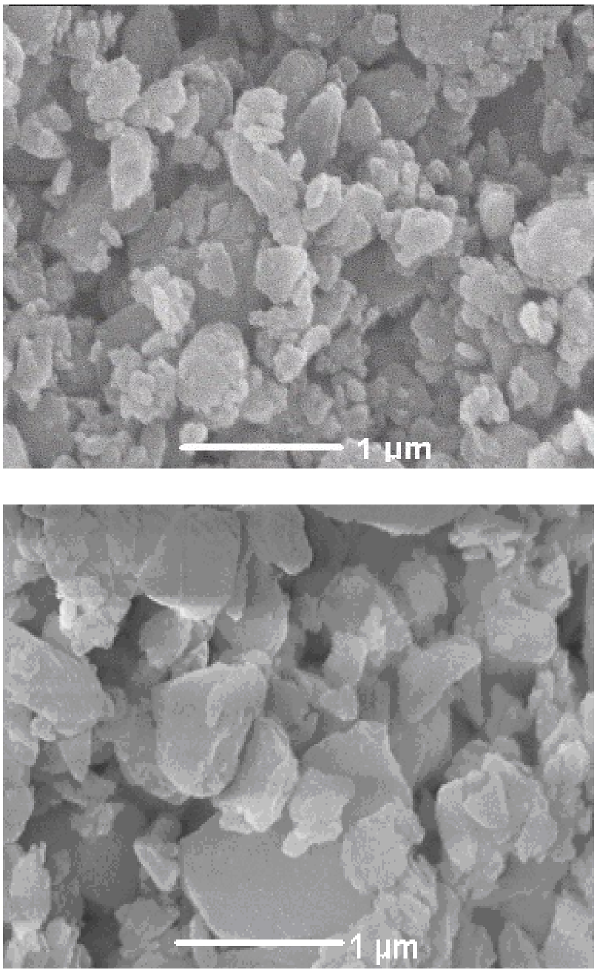


Fig. 1a,b: Barium aluminium silicate glass fillers with a mean particle size of 0.4 µm (left picture) and 0.7 µm (right picture) as used in Tetric EvoCeram Bulk Fill.

Isofiller

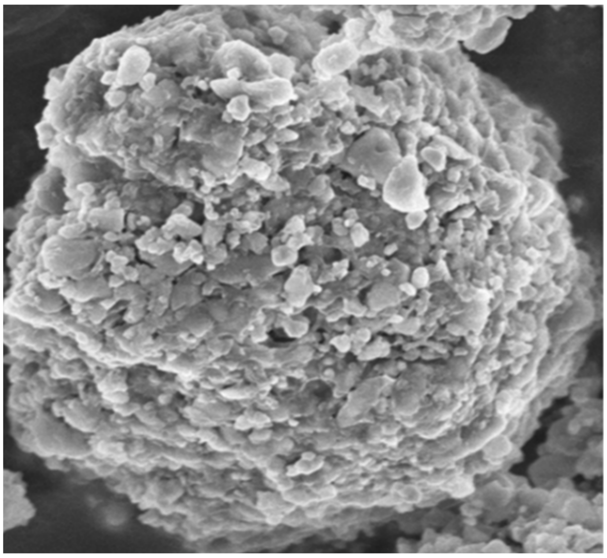


Fig. 2: *Isofiller* composed of cured dimethacrylates, glass filler and ytterbium fluoride

Ytterbium fluoride

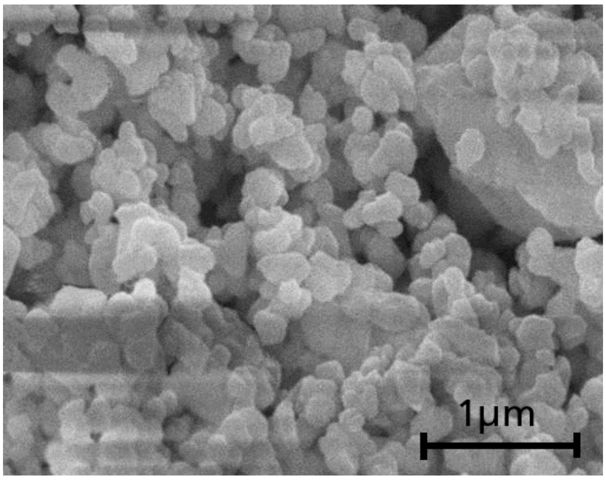


Fig. 3: Ytterbium fluoride with a mean particle size of 200 nm

Spherical mixed oxide

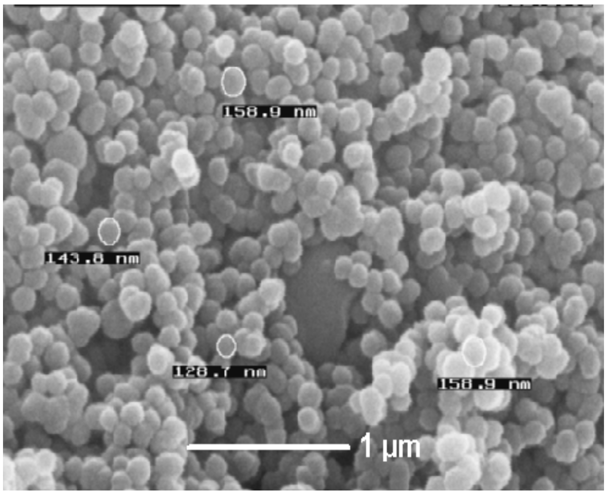


Fig 4: Mixed oxide of a mean particle size of 160 nm

Glass fillers result in low wear and favourable polishing properties i.e. low surface roughness and high gloss. “Isofillers” are instrumental in lowering the shrinkage and shrinkage stress. Tetric EvoCeram Bulk Fill utilises a specially designed shrinkage stress relieving “Isofiller” which is discussed in more detail below (2.2.2). Ytterbium fluoride confers high radiopacity to dental materials and is capable of releasing fluoride. Spherical mixed oxide provides the basis for reduced wear and favourable consistency. The spherical particles minimise the thickening effects of fillers, as they provide the largest volume with the smallest surface area possible. Primary particles, (individual bodies) and secondary particles (agglomerates) combine to form the ideal consistency. Mixed oxide also provides aesthetic advantages, as the refractive index is matched to that of the matrix (polymer) meaning light can pass through the medium (restoration) unhindered. This results in restorations that are virtually indiscernible from the surrounding tooth structure.

Fig. 5: Illustration of refractive index with glass rods in water (left) and monomer mixture with coordinated refractive index (right)

The picture above illustrates the principle of coordinating the refractive indices of the fillers and the matrix. The glass on the left contains water with a refractive index of 1.33. The glass on the right contains a monomer mixture with a refractive index set at 1.51 i.e. the same as the glass rod. Thus if the refractive index of the fillers corresponds to that of the matrix as in the right hand glass, the structure is virtually invisible as the light is not refracted differently.

The pictures below show the aesthetic results possible with Tetric EvoCeram Bulk Fill, the restorations shown in Fig. 6b are virtually indiscernible from the surrounding tooth structure.

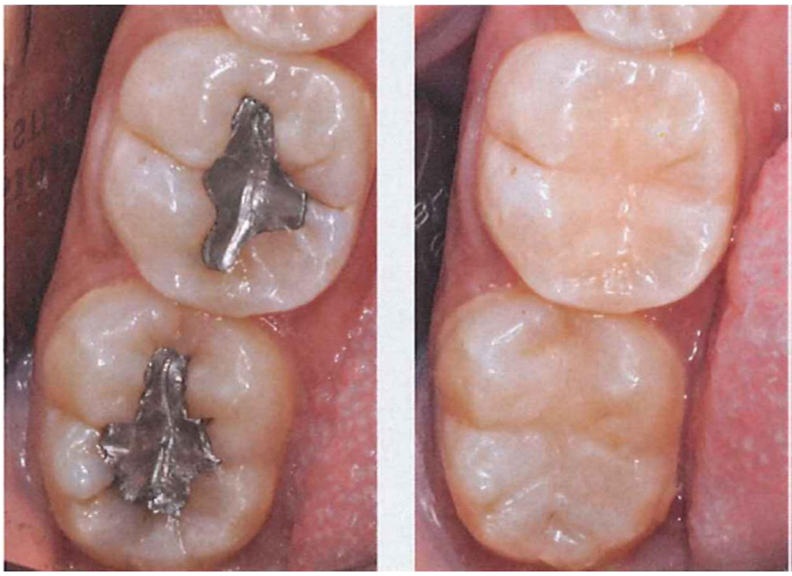


Fig 6a,b: Replacement of original posterior amalgam fillings (left) with Tetric EvoCeram Bulk Fill restorations (right).

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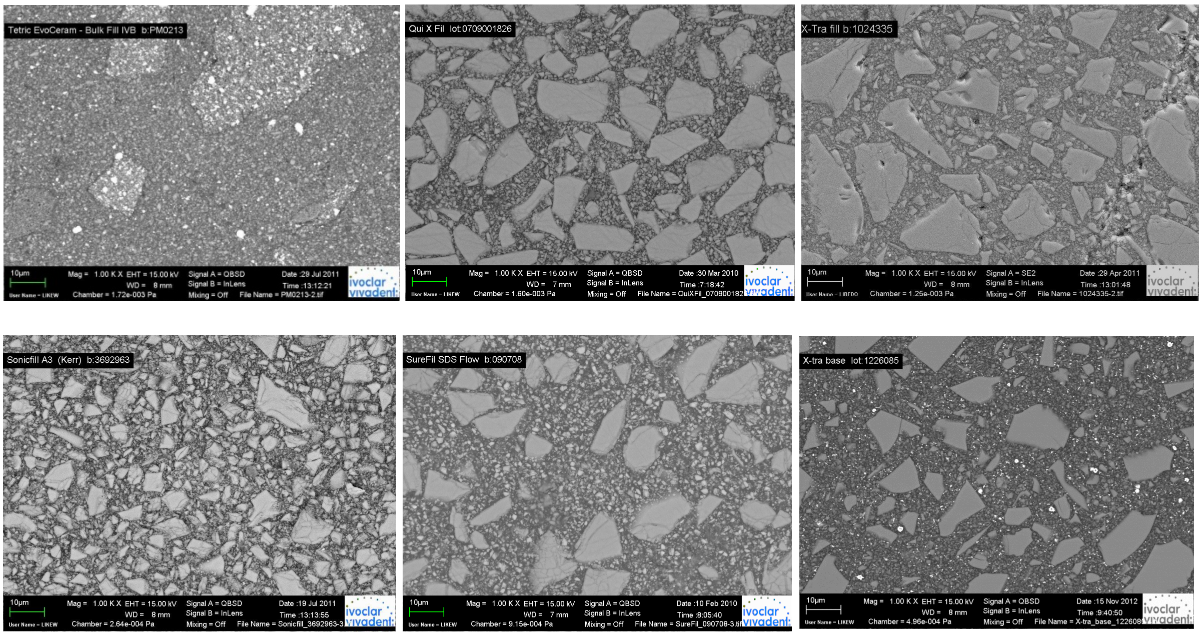
2.2.1 *Filler size and polishability*

The mix and size of the fillers are responsible for the excellent polishability and high gloss of Tetric EvoCeram Bulk Fill. It comprises fillers of comparatively small size as large fillers are unable to produce the same smooth, glossy surface as small fillers. The scanning electron microscope (SEM) images below show the clear differences in filler size of Tetric EvoCeram Bulk Fill (top left) compared to other composite materials.



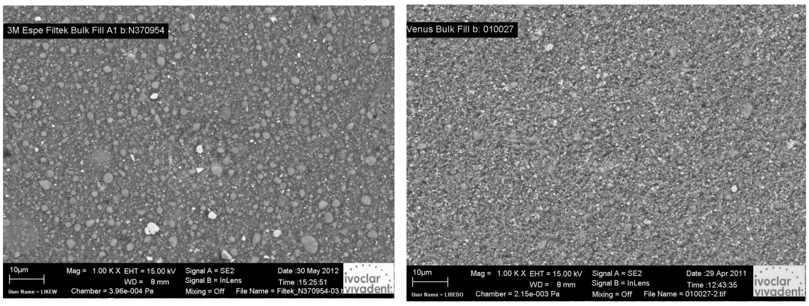


Fig. 7a-h: SEM images of various composite materials. *(R&D Ivoclar Vivadent 2011)*

Apart from Filtek Bulk Fill/3M Espe (bottom, left) and Venus Bulk Fill/Heraeus Kulzer (bottom middle), all the other materials contain relatively large fillers. This correlates with the polishing results shown in section 4.5.

2.2.2 *Shrinkage stress reliever*

Tetric EvoCeram Bulk Fill can be applied in increments of up to 4mm. Clearly reducing polymerisation shrinkage is one of the most important issues here. Composite resins shrink during polymerisation which was the original rationale behind applying composites in 2 mm increments with successive polymerisation intervals. Problems associated with polymerisation shrinkage include marginal discolouration, marginal gaps, secondary caries, cracking and hypersensitivity. Shrinkage stress in Tetric EvoCeram Bulk Fill is however kept to a minimum. A special patented filler which is partially functionalised by silanes, acts as a unique shrinkage stress reliever. The following diagram illustrates this mechanism:

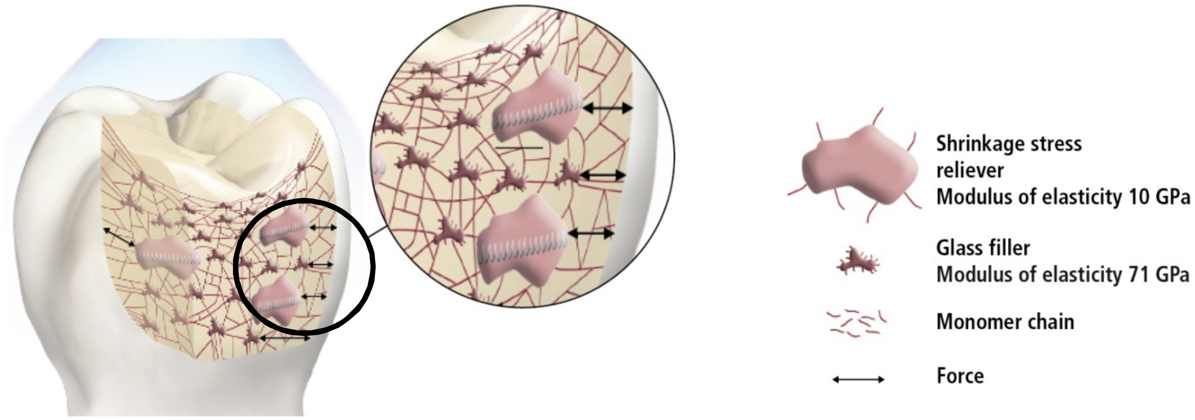


Fig. 8: Schematic representation of the shrinkage stress reliever in a Tetric EvoCeram Bulk Fill restoration acting like a spring and reducing stress within the restoration

When the composite is cured, the monomer chains located on the fillers together with the silanes begin a cross-linking process and forces between the individual fillers come into play and place stress on the cavity walls. This stress is influenced by both volumetric shrinkage and the modulus of elasticity of the composite. A high modulus of elasticity denotes inelasticity and a low modulus of elasticity denotes higher elasticity. Due to its low elastic modulus (10 GPa) the shrinkage stress reliever within Tetric EvoCeram Bulk Fill acts like a spring (expanding slightly as the forces between the fillers grow during polymerisation) amongst the standard glass fillers which have a higher elastic modulus of 71 GPa. The shrinkage stress reliever essentially "holds on" to the cavity walls along with the matrix and the adhesive.[8] The silanes bonded to the filler particles improve the bond between the inorganic filler (glass and quartz particles) and the monomer matrix as they are able to establish a chemical bond between the glass surface and the matrix. Ultimately, the volumetric shrinkage and shrinkage stress in Tetric EvoCeram Bulk Fill are reduced during polymerisation – allowing increments of up to 4mm to be placed whilst ensuring a tight marginal seal.

2.3 Polymerisation technology

Light-curing composites "set" by way of free radical polymerisation. Incoming photons from the curing light are absorbed by photoinitiators. The energy absorbed excites the molecules, and enables the formation of free radicals (if one or several activators are present) and this triggers polymerisation. The darker and/or the more opaque a material is, the shallower the depth of cure because less light can reach the initiators within the composite. It is often not possible to polymerise thick increments reliably unless the material is highly translucent or contains somewhat limited amounts of light-refracting fillers. Conventional initiator systems alone are unable to cure increments exceeding 2 mm reliably.

Initiator molecules are only able to absorb photons within a specific spectral range. Camphorquinone, an initiator widely used in polymer synthesis has a light absorption spectrum of approximately 390 nm to 510 nm, with a peak sensitivity of 470 nm. Camphorquinone reacts to visible light in the blue range. It has an intense yellow hue due to its absorption properties, thus other initiators such as Lucirin TPO an acyl phosphine oxide which bleaches out entirely after polymerisation, tend to be used for composite bleach shades or colourless protective varnishes. Lucirin TPO has a considerably lower sensitivity peak than camphorquinone.

2.3.1 Light initiator Ivocerin®

Tetric EvoCeram Bulk Fill utilises the above mentioned initiators camphorquinone plus an acyl phosphine oxide together with a newly patented initiator Ivocerin®. It is standard in dentistry to apply composites in individually cured, 2 mm increments, as larger layers would negatively affect the depth of cure. In order to increase the possible increment depth all parameters influencing depth of cure such as translucency, colour, initiator types and concentration plus curing time and light intensity have to be considered. The new light initiator Ivocerin® - a dibenzoyl germanium derivative [20,21] plays an important role here. It allows the application and curing of posterior restorations in larger increments of up to 4mm, without compromising the optical properties of the composite such as translucency or colour.

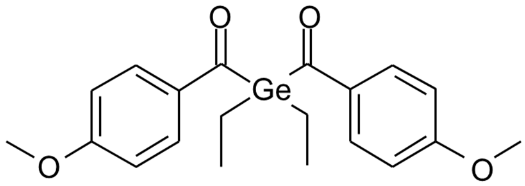


Fig. 9: Structural formula of germanium based photoinitiator Ivocerin®

Ivocerin® and light absorption

The standard initiator system plus Ivocerin® results in a material featuring an absorption maximum in the blue light range from around 370 to 460 nm.[8] The initiator absorption spectra are depicted below in figures 10 and 11.

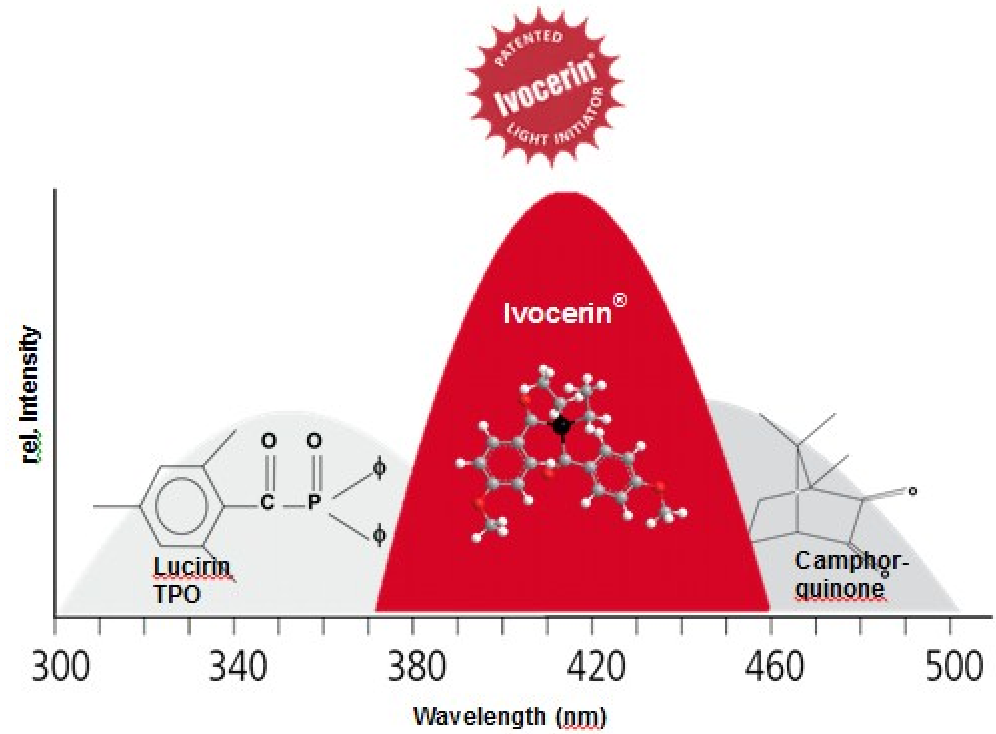


Fig. 10: Schematic representation of the absorption spectra of Lucirin TPO, Camphorquinone and Ivocerin®

Ivocerin® features a high absorption coefficient (higher than camphorquinone) allowing for increased quantum efficiency. The initiator is far more light-reactive than camphorquinone or Lucirin TPO, enabling the material to polymerise more rapidly and with a greater depth of cure. In this sense it acts as a polymerisation booster.

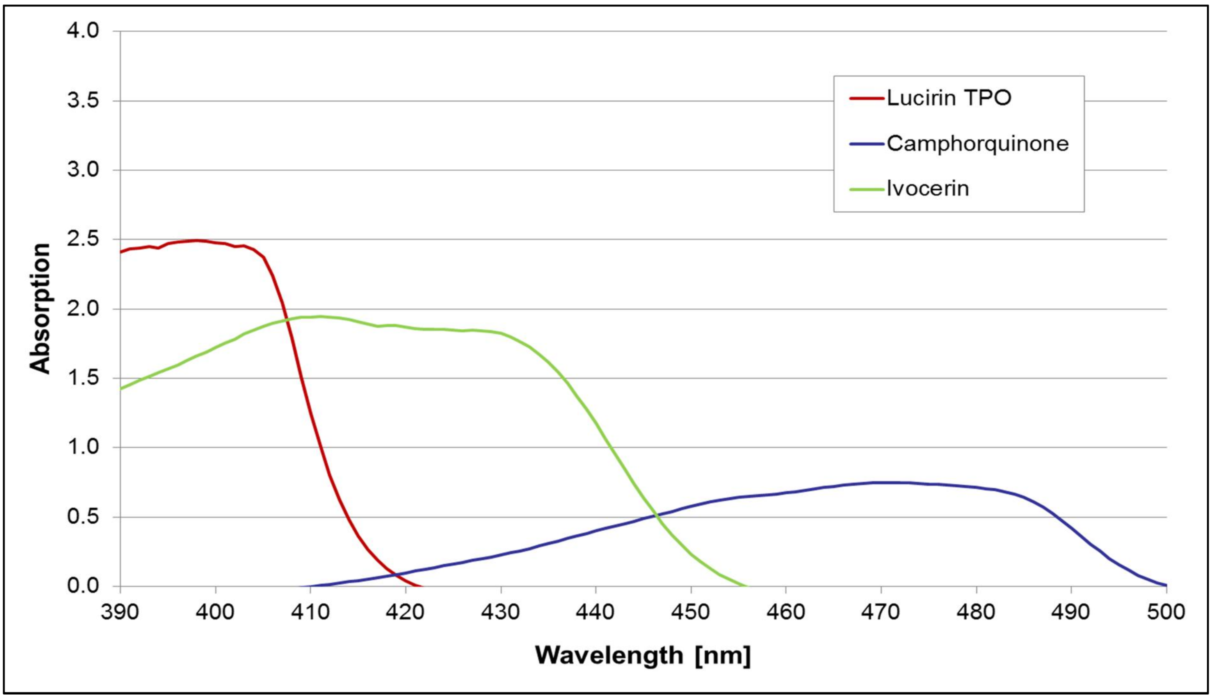


Fig. 11: Absorption spectra of Lucirin TPO, camphorquinone and Ivocerin® as measured in the laboratory. *(R&D Ivoclar Vivadent 2012)*

Ivocerin® and aesthetics

All standard initiators are yellow, as this is the complementary colour to blue light – with which all standard composites are polymerised. Although the yellow colour largely disappears during curing, a slight hue will always remain. This is however deemed acceptable as natural teeth are also slightly yellow in colour. Lucirin TPO absorbs light largely in the UV-area and thus has just a very slight yellow colour making it highly suitable for composite bleach shades.

Ivocerin® **Lucirin TPO** **Camphorquinone**



Fig. 12a-c: Light initiators contained in Tetric EvoCeram Bulk Fill in their pure form:

Ivocerin® is also yellow in colour, but can be used in relatively small quantities due to its enhanced reactivity. This is useful as it means its properties can be used without negatively affecting the optical properties of tooth-coloured pastes with enamel-like translucency.

The following diagram illustrates the optimal translucent properties of Tetric EvoCeram Bulk Fill as compared to various other bulk fill composites. In order to simulate dentin discoloration the central slightly higher occlusal section of the cavity was stained with IPS Empress Direct Color in grey. The approximal area was not stained. The filling on the left with Tetric EvoCeram Bulk Fill (15% translucency) is the most aesthetic, the grey is camouflaged and the composite blends with the surrounding "tooth". Venus Bulk Fill however (middle tooth) is visibly transparent (38.6% translucency) in comparison.

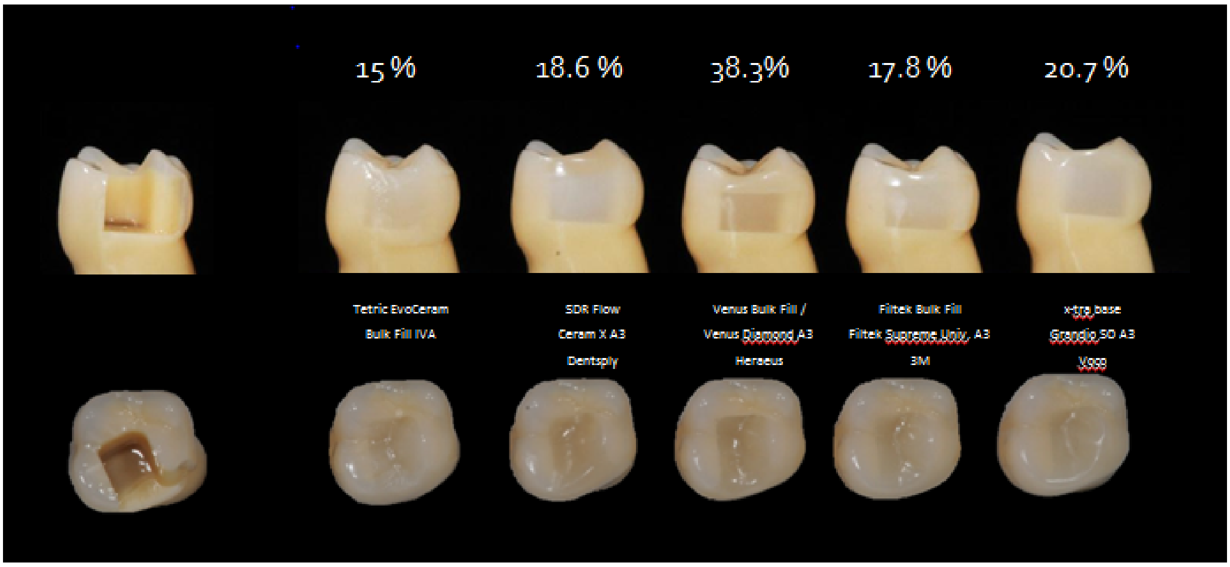


Fig. 13: Various bulk fill composites showing varying translucency and corresponding aesthetics. (R&D Ivoclar Vivadent 2013)

Ivocerin® and depth of cure

The polymerisation booster Ivocerin® allows Tetric EvoCeram Bulk Fill to be set to an enamel-like translucency of 15%. This is sufficient such that when exposed to the light of a high energy curing unit such as Bluephase Style, the restoration cures reliably. Whilst the number of photons that reach the cavity floor is significantly lower than the number that reach the surface, it is sufficient for Ivocerin® to trigger polymerisation at a depth of 4mm.

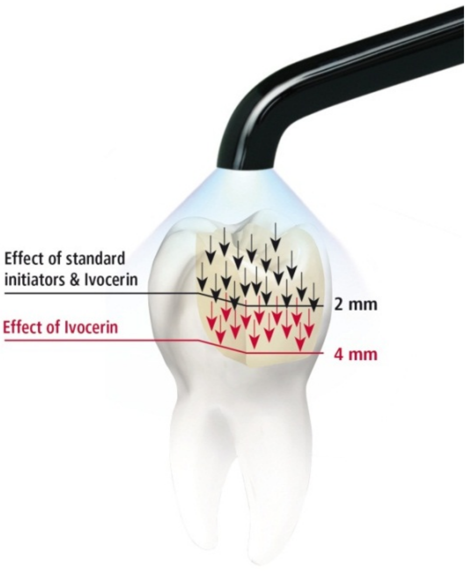


Fig. 14: Effect of Ivocerin® polymerisation booster on light curing (10s ≥ 1000 mW/cm²)

2.3.2 Light sensitivity filter

A material that is applied in 4 mm increments and subsequently contoured needs to provide sufficient working time before the product begins to polymerise. The longer the working time the more user-friendly the product. As composite materials generally contain photoinitiators that react to blue light, both ambient light and dental operating lights (which contain blue light) are capable of triggering premature polymerisation.

Tetric EvoCeram Bulk Fill incorporates a patented light sensitivity filter to prevent premature polymerisation. This provides a working time of more than three minutes under defined light conditions of 8000 lux.[9] (See section 4.2, figure 19).

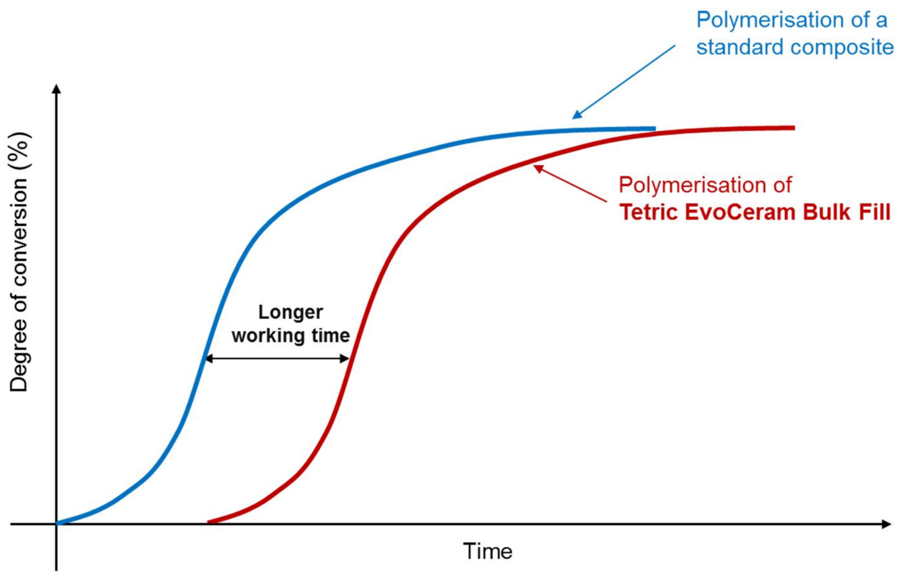


Fig. 15: Schematic representation: Light sensitivity filter delays polymerisation in ambient light.

Importantly whereas the stabiliser/inhibitor delays the polymerisation process in the presence of “low level” blue light, it does not impair curing under the intensive blue light of a polymerisation unit.

2.4 Conclusion: Paradigm shift from 2 mm to 4 mm increments

Before the introduction of bulk fill composites, standard dental teaching recommended a maximum layer thickness for composite fillings of 2mm.[10,11] This was in order to minimise shrinkage stress and to ensure adequate depth of cure. Notably in deep cavities, placing such restorations can be time consuming and with many layers involves the not insignificant risk of incorporating air bubbles.[8]

Due to the incorporation of the polymerisation booster Ivocerin®, a light sensitivity filter and a shrinkage stress reliever, a real paradigm shift in dentistry is now possible.

Tetric EvoCeram Bulk Fill is an aesthetic time-saving composite that can be applied efficiently in 4 mm increments.

3. Technical Data

Tetric EvoCeram Bulk Fill

Standard composition (in weight %)

Dimethacrylates	19.7
Prepolymer	17.0
Barium glass filler, Ytterbium trifluoride, Mixed oxide	62.5
Additive, Initiators, Stabilisers, Pigments	< 1.0

Physical properties

In accordance with:
EN ISO 4049:2009 Dentistry – Polymer-based restorative materials (ISO 4049:2009)

		Specification	Example value
Flexural strength	MPa	≥ 80	120
Water sorption (7 days)	µg/mm³	≤ 40	21.1
Water solubility (7 days)	µg/mm³	≤ 7.5	< 1.0
Radiopacity	% Al	≥ 100	260

Other physical properties

Vickers hardness HV 0.5/30	MPa	620
Flexural modulus	MPa	10000
Layer thickness (IV Method)	mm	4.0
Transparency: (depending on opacity)	%	15 - 17

4. Materials Science Investigations / In Vitro

4.1 Depth of cure

Assuming correct adequate curing with a suitably functioning curing unit, translucency and shade have the most significant effect on the curing depth. The darker and more opaque a composite, the lower the curing depth,[12] but if manufacturer instructions are followed closely a good degree of cure is usually obtained on the surface of a composite, irrespective of translucency or shade.[13] Assessing cure across the entire thickness of a restoration in vivo is however impossible.

ISO 4049: Depth of cure

The international standard ISO 4049 for polymer based restorative materials suggests measuring depth of cure via preparing cylindrical specimens 6mm long and 4mm wide, or if a depth of cure greater than 3mm is claimed the length should be at least 2mm longer than twice the claimed depth of cure. After curing according to the manufacturer's instructions, the material is removed from its mould, the inhibition layer and other uncured material is scraped away and the height of the remaining material is measured. This value divided by 2 is considered to be the depth of cure. This method does not account for post-irradiation polymerisation.

Vickers/Knoop hardness: Depth of cure

There are a number of in vitro test methods for establishing depth of cure. Vickers hardness and Knoop hardness profiles of the cured material are suitable and can be conducted some time after curing, allowing for post-irradiation polymerisation.

The Vickers hardness test utilises a diamond pyramid shaped indenter that is ground in the form of a squared pyramid with an angle of 136° between faces and the depth of indentation is about 1/7 of the resulting impression's diagonal length.

The Knoop hardness test utilises a diamond elongated pyramid shaped indenter that is ground to an elongated pyramidal form that produces a diamond shaped indentation with a depth of indentation of about 1/30 of the indentation's length.

Cured specimens are usually prepared in cylindrical moulds and the hardness at the top and bottom of the cylinder is measured to obtain a simple single hardness measure. For a hardness profile throughout the material, cured specimens are cut vertically into two pieces. The cut surfaces are polished and the hardness is determined at intervals from the top to the bottom. Hardness is often expressed as a percentage of the surface hardness which is considered 100%.[13] Experience has shown that the simple hardness measures (top and bottom) correspond well to the more thorough hardness profile measurements.[14] According to research carried out by Professor David Watts of the University of Manchester, UK, an acceptable curing depth is achieved, if the bottom hardness corresponds to at least 80% of the surface hardness.[15]

Measurements have shown that the degree of cure decreases continuously in areas deeper than approximately 0.5 mm. The degree of cure is highest at a depth of 0.55 mm, because of the uppermost inhibition layer. From this layer downwards, the light intensity entering the material decreases steadily as filler particles scatter light and colour pigments absorb it. A post-light-curing reaction with remaining radicals tends to occur within 24 hours after initial polymerisation and this is also accompanied by a decrease in the yellowish tinge if camphorquinone is used as a photoinitiator. Thus to determine depth of cure, test samples are usually stored for 24 hours before measurements are made. A number of internal and external investigations confirm the adequate depth of cure at 4mm in Tetric EvoCeram Bulk Fill.

Depth of cure of Tetric EvoCeram Bulk Fill cured with Bluephase G2 and Bluephase Style in comparison to other composites. Dr A. Rzanny, M Fachet, Universitätsklinikum Jena, Germany. (July 2012)

Rzanny et al aimed to establish the suitability of the Bluephase Style curing unit alongside Bluephase G2 regarding depth of cure in various composites. Both the depth of cure using a Penetrometer and Vickers hardness values were calculated for the composites Tetric EvoCeram (A3), Tetric EvoCeram Bulk Fill (IVA) and Venus Bulk Fill (Universal) when cured for 10 seconds with Bluephase (G2) (1200 mW/cm^2) or Bluephase Style (1100 mW/cm^2) .

Methods

Depth of cure

Specimens with a diameter of 6mm and a height of 10mm were fabricated and cured for 10 seconds with either of the lamps. The length of the cured sections of the material were calculated immediately after polymerisation. A Penetrometer (AP4/3 Feinmess Dresden) was used to measure the depth of the uncured material on the underside. The difference in length was then divided by two (as stipulated in the standard DIN EN ISO 4049).

Vickers hardness

Each composite was applied in a 4mm high and 8mm wide Teflon mould and covered with a foil at the top and bottom. The light guide of the respective lamp was placed directly onto the foil and the composite cured for 10 seconds. Vickers Hardness was calculated (Load 5kg/20s) via a Zwick 3212 machine at 23°C on the surface and bottom of the sample (4mm depth) – immediately after polymerisation, 24 hours later and 7 days later.

Results

Depth of cure (ISO 4049 Method)

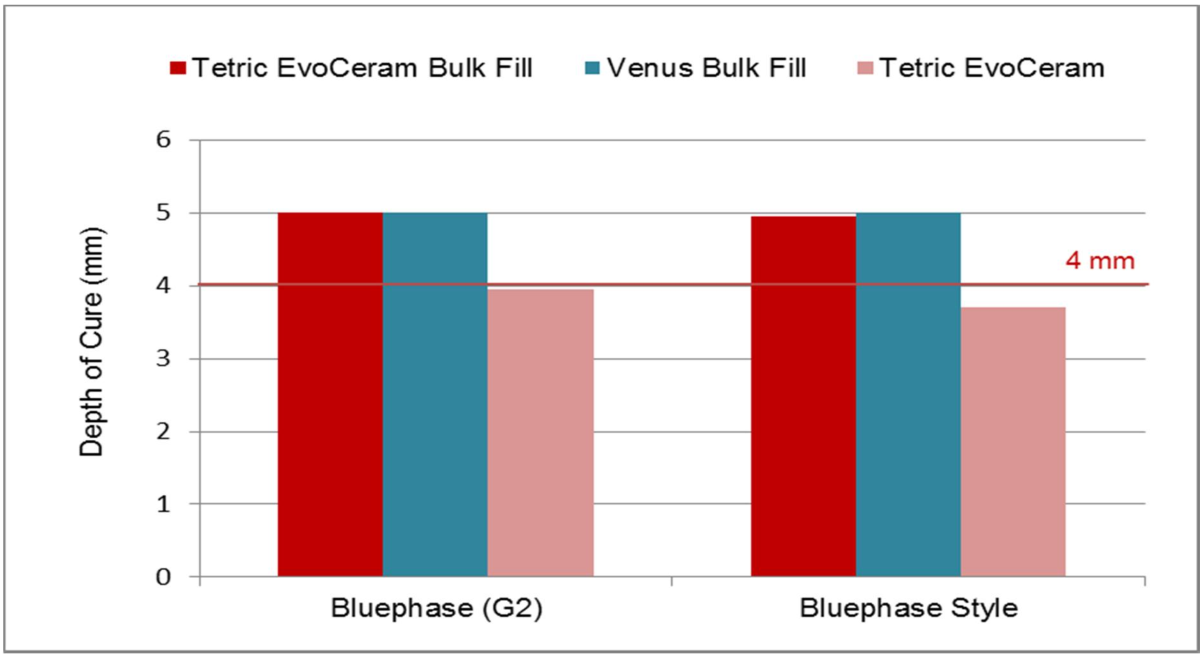


Fig. 16: Depth of cure for various composites when cured with Bluephase (G2) and Bluephase Style for 10 s. (*Dr A. Rzanny, M Fachet, Universitätsklinikum Jena, Germany)*

There was no significant difference between curing lamps for any of the composites. Both bulk fill composites Tetric EvoCeram Bulk Fill and Venus Bulk Fill far exceeded the manufacturer indicated allowable increment thickness (4 mm) in terms of depth of cure. Tetric EvoCeram is not a bulk fill composite and is intended to be applied in 2mm increments.

Vickers hardness
It is generally accepted that an adequate depth of cure has been achieved if the bottom hardness corresponds to at least 80% of the surface hardness.[15] The Vickers hardness results for Tetric EvoCeram Bulk Fill all exceeded the 80% ratio necessary. When cured with Bluephase (G2) the ratio was 87.6% after 24 hours and 83.6% after 7 days. When cured with Bluephase Style it was 80.3% after 24 hours and 87.5% after 7 days.

Conclusion
The authors conclude that both Bluephase (G2) and Bluephase Style are equally suitable for polymerising the three composites investigated. After 1 day storage, both bulk fill products achieved the necessary 80% hardness ratio.

Vickers hardness of 4 mm specimens of all shades: R&D Ivoclar Vivadent, Schaan, Liechtenstein. (July 2011)
Internal investigations support the results from Rzanny et al. Vickers hardness measurements were taken at a depth of 4mm. The following figures illustrate the hardness values of all three Tetric EvoCeram Bulk Fill shades: IVA, IVB and IVW – both at the surface and at a depth of 4mm. The values measured at the top were set to 100% and the values measured at 4 mm are expressed as a percentage of this value. Various light intensities were employed and the curing times were adjusted accordingly to ensure a similar light output in each case. For each of the shades the 4mm hardness value exceeded 80% of the surface hardness under all curing settings.

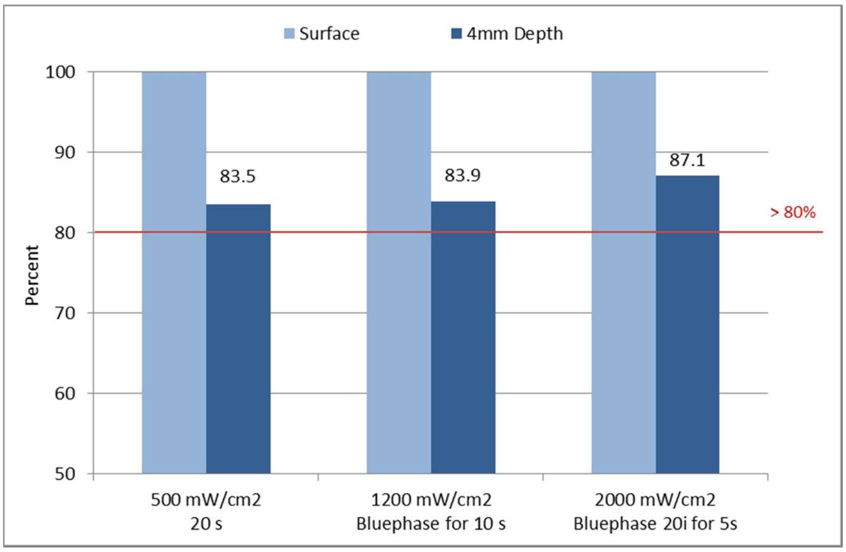


Fig. 17a: Tetric EvoCeram Bulk Fill **Shade IVA**: 4 mm depth hardness as percentage of surface hardness, measured with different light intensities

(R&D Ivoclar Vivadent, Schaan, 2011)

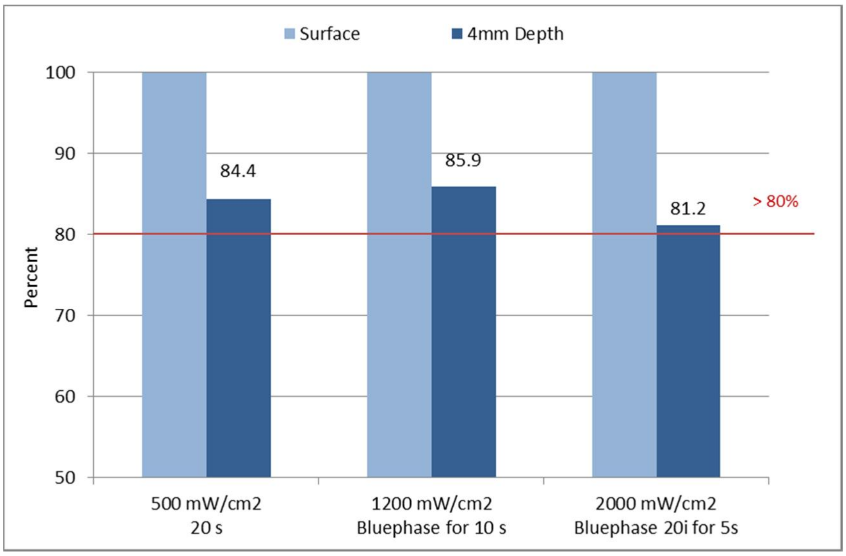


Fig. 17b: Tetric EvoCeram Bulk Fill **Shade IVB**: 4 mm depth hardness as percentage of surface hardness, measured with different light intensities

(R&D Ivoclar Vivadent, Schaan, 2011)

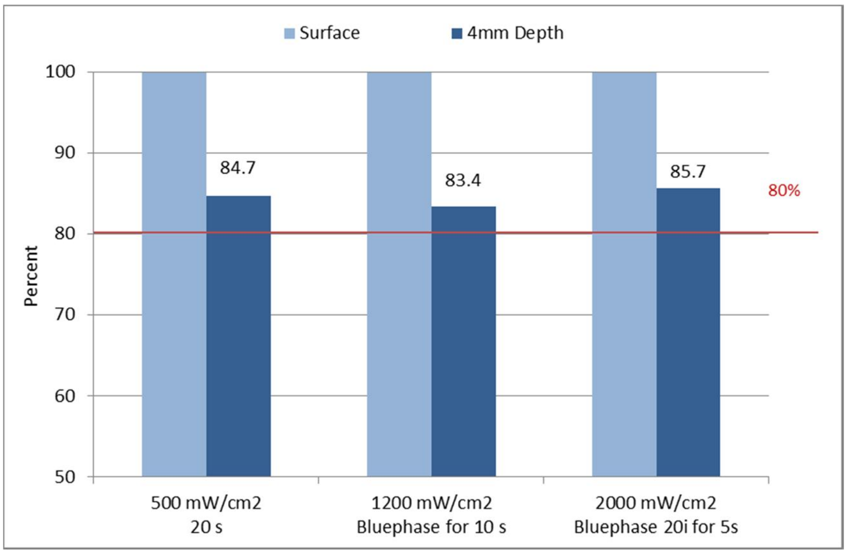


Fig. 17c: Tetric EvoCeram Bulk Fill **Shade IVW**: 4 mm depth hardness as percentage of surface hardness, measured with different light intensities

(R&D Ivoclar Vivadent, Schaan, 2011)

Evaluation of the depth of cure and surface micro hardness of a new bulk fill composite system. Sabatini C. Dental Biomaterials Research Laboratory. State University of New York at Buffalo. (October 2012)

Sabatini evaluated the depth of cure and surface microhardness of Tetric EvoCeram Bulk Fill, two further bulk fill products: x-tra fil/VOCO, Sonic Fill/KERR and Tetric EvoCeram as a control.

Method

Two light curing units were employed: Bluephase G2 (1200 mW/cm^2) and Bluephase 20i Turbo (2000 mW/cm^2) with exposure times of 10 and 5 seconds respectively. This yielded a total of 8 study groups for which 10 samples were fabricated (n=80)

	x-tra fil	Sonic Fill	Tetric EvoCeram Bulk Fill	Tetric EvoCeram
Bluephase G2	XF-G2 n=10	SF-G2 n=10	TB-G2 n=10	TEC-G2 n=10
Bluephase 20i	XF-20i n=10	SF-20i n=10	TB-20i n=10	TEC-20i n=10

Table 3: Eight study groups according to material and light source – showing abbreviation and sample size (n=80). (*Sabatini October 2012)*

All specimens were prepared in standardised moulds (6 x 6 mm) and polymerised according to manufacturer instructions. Specimens were removed from the moulds taking care not to disturb the inhibition layer at the top. Any unpolymerised material was scraped away from the bottom and specimens were stored undisturbed in a dark environment in 100% humidity at 37°C for 24 hours, after which micro-hardness tests were recorded.

Knoop hardness tests were carried out on specimens on the top and bottom surfaces using a Leco M-400 hardness tester with a load of 300 g. After embedding the samples horizontally in an acrylic resin block the samples were then ground down to half their diameter and the internal surfaces polished. All procedures were performed under controlled lighting. Knoop hardness measures were then recorded at 0.5 mm intervals from the top to the bottom. Hardness measurements at a depth of 4mm for x-tra fil and Tetric EvoCeram Bulk Fill, 5mm for Sonic Fill and 2mm for Tetric EvoCeram were used to calculate the top/bottom hardness ratios to determine whether the composite system met the generally accepted hardness ratio of 80% for an adequate depth of cure.

Results

Two way analysis of variance (ANOVA) revealed no difference in bottom/top hardness values for the type of polymerisation unit used. However significant differences were found between certain restorative composites cured with the same light source ($p < 0.001$)

	x-tra fil (4mm)	Sonic Fill (5mm)	Tetric EvoCeram Bulk Fill (4m)	Tetric EvoCeram (2mm)
Bluephase G2	70.6 %	47.1 %	85.7 %	85.1 %
Bluephase 20i	69.4 %	55.6 %	86.9 %	81.4 %

Table 4: Bottom/Top hardness ratios at the recommended increment thickness per material. (*Sabatini October 2012)*

When polymerised with Bluephase G2 there were no significant differences between x-tra fil, Tetric EvoCeram Bulk Fill and Tetric EvoCeram but all were significantly different to Sonic Fill. When polymerised with Bluephase 20i, there were also no significant differences between x-tra fil, Tetric EvoCeram Bulk Fill and Tetric EvoCeram however Sonic Fill was significantly lower than Tetric EvoCeram Bulk Fill and Tetric EvoCeram but not significantly lower than x-tra fil. Notably both Tetric EvoCeram Bulk Fill at 4mm and Tetric EvoCeram at 2mm fulfilled the Watts criterion with all figures exceeding 80%.

The diagram below shows the bottom/top hardness ratios at different depths for Tetric EvoCeram Bulk Fill when cured with both Bluephase lights.

	Top	0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm	Bottom
Bluephase G2	100	120.7	110.6	100	100.4	95.8	95.8	88.1	85.7	64.4	67.4	56.1	32.3
Bluephase 20i	100	149.4	165.2	137.6	145.2	133.9	119.6	106.8	86.9	82.7	67.4	41.3	32.9

Fig. 18: Bottom/top Knoop hardness ratios at 0.5mm increments for Tetric EvoCeram Bulk Fill. (*Sabatini October 2012)*

Conclusion

Tetric EvoCeram Bulk Fill achieved in excess of the necessary 80% bottom/top hardness ratio at a depth of 4mm independent of the light source. Tetric EvoCeram also achieved this at a depth of 2 mm. Tetric EvoCeram Bulk Fill achieved significantly higher hardness ratios than Sonic Fill/KERR.

Curing duration vs. depth of cure and modulus of bulk fill composites. S. Zawawi, N. Brulat, and Prof. D. Nathanson, Restorative Sciences and Biomaterials, Boston University, Boston, MA, USA. (2012) [16]

In vitro testing was carried out to evaluate the effect of curing duration on the depth of cure and modulus of elasticity in bulk fill composites.

Method

Cylindrical resin specimens (4 mm x 8 mm) were prepared from three different composite materials: Tetric EvoCeram Bulk Fill, Surefil SDR/Dentsply and Venus Bulk Fill/Heraeus Kulzer. The Bluephase 16i (1600 mW/cm^2) curing light was used to cure the composites for either 10 or 40 s. Specimens were then sectioned longitudinally and polished. Depth of cure was assessed using Vickers Hardness (100 g, 20 s) measurements at depths of 2 mm, 4 mm and 6 mm. Sixteen measurements for each test parameter were conducted. To assess the modulus of elasticity, specimens were formed into bars (4 mm x 25 mm x 2 mm) and tested in flexural mode using an Instron machine. Results were analysed with ANOVA.

Results
The Vickers hardness values for the composites at the surface and at a depth of 2 mm, 4 mm and 6 mm when cured for 10 s or 40 s are shown below in Fig. 19. Tetric EvoCeram Bulk Fill exhibited higher microhardness than SureFil SDR and Venus Bulk Fill at all depths and curing times.

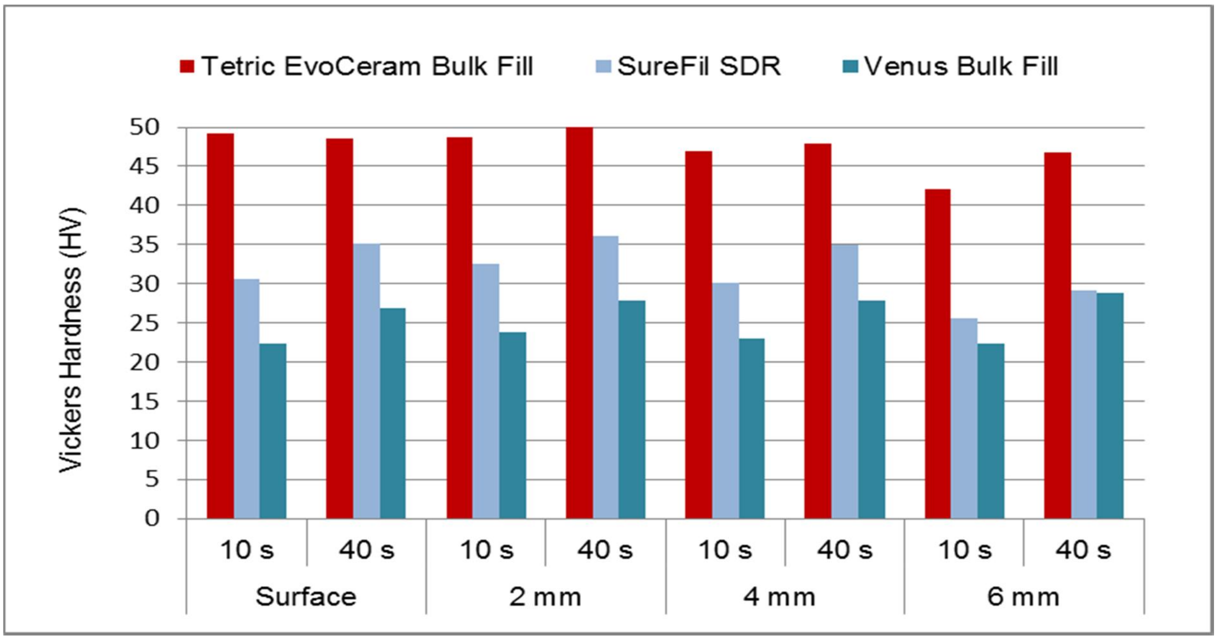


Fig. 19: Microhardness (HV) of various composites at various depths and curing times. (*S. Zawawi, Boston University, USA)*

The mean modulus of elasticity was also measured for each bulk fill composite with both 10 s and 40 s of curing. There was no significant difference between Tetric EvoCeram Bulk Fill samples when cured for 10 seconds or 40 seconds. However there were significant differences in modulus between the different materials at both 10 and 40 s. ($p < 0.5$). Whereas curing duration had no significant effect on the modulus of elasticity for Tetric EvoCeram Bulk Fill this was not the case for SureFil SDR or Venus Bulk Fill – where there was a clear difference (increase) between 10 and 40 s polymerisation time.

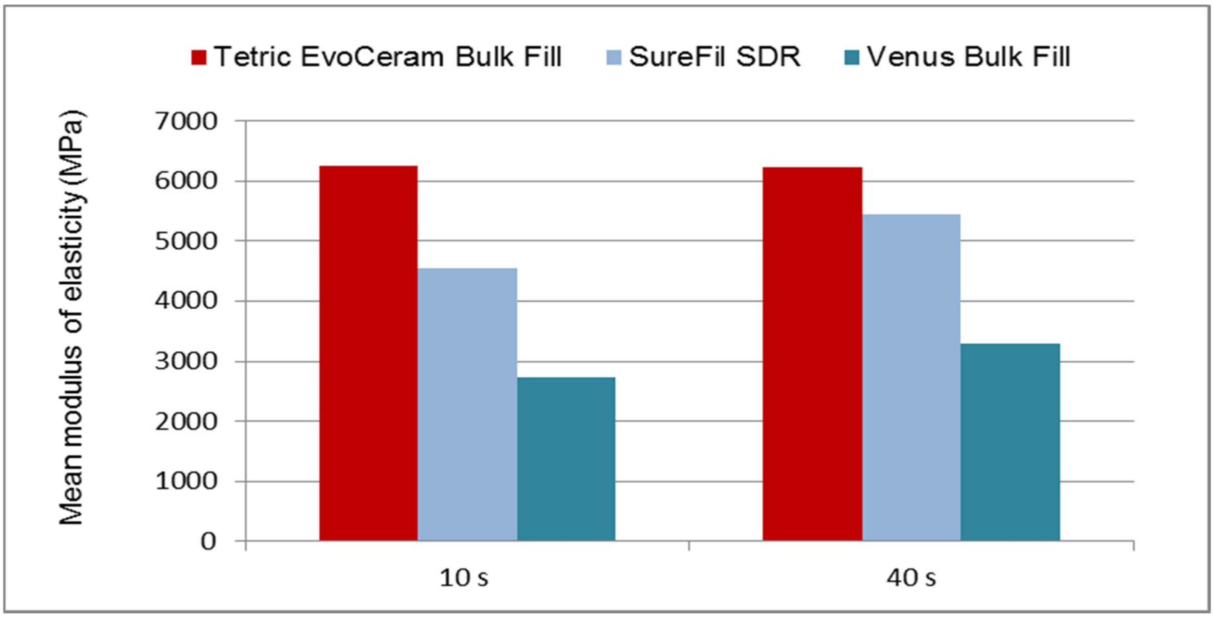


Fig. 20: Mean modulus of elasticity of various composites when cured for 10 s vs. 40 s. (*S. Zawawi, Boston University, USA)*

Conclusion
Both the Vickers hardness and modulus of elasticity are related to depth of cure. Microhardness can be determined at various depths and the higher the modulus of elasticity the greater the amount of cross-linkage i.e. polymerisation that has occurred. Tetric EvoCeram Bulk Fill achieves higher mechanical properties than the other products and is almost indifferent to the length of cure (10 s vs. 40 s).

Notably the bottom/surface ratio of the Vickers hardness for Tetric EvoCeram Bulk Fill at 4mm (10 s = 95.5%, 40 s = 98.5%) and even at 6mm (10 s = 85.7%, 40 s = 96.2%) is way beyond the generally accepted 80% level.

4.2 Light insensitivity

The time available to apply and contour a composite material before it starts to polymerise plays an important role in determining its user friendliness.

Composite materials normally contain photoinitiator systems that react to the blue light portion of the visible light spectrum. The source of that blue light is immaterial. As both daylight and dental operating lights comprise a certain amount of blue light, they can contribute to the (premature) polymerisation of composite materials. The higher the intensity of the ambient light, the shorter the working time before the material begins to polymerise. Protecting light curing materials from ambient light during application is impractical and with dental loupes becoming more popular, very light-sensitive composites have a clear disadvantage.

Tetric EvoCeram Bulk Fill therefore features a patented light sensitivity filter. The inhibitor delays polymerisation when low level blue light is present, but does not impair the polymerisation process under the intensive blue light of a properly functioning curing light.

A material's sensitivity to ambient light is usually determined according to conditions defined in the standard ISO 4049. The longer the period of time before the material polymerises, the less sensitive to light it is. Tetric EvoCeram Bulk Fill features a working time of more than three minutes (200 s) under defined light conditions of 8000 lux. This was the longest working time of the materials tested below.

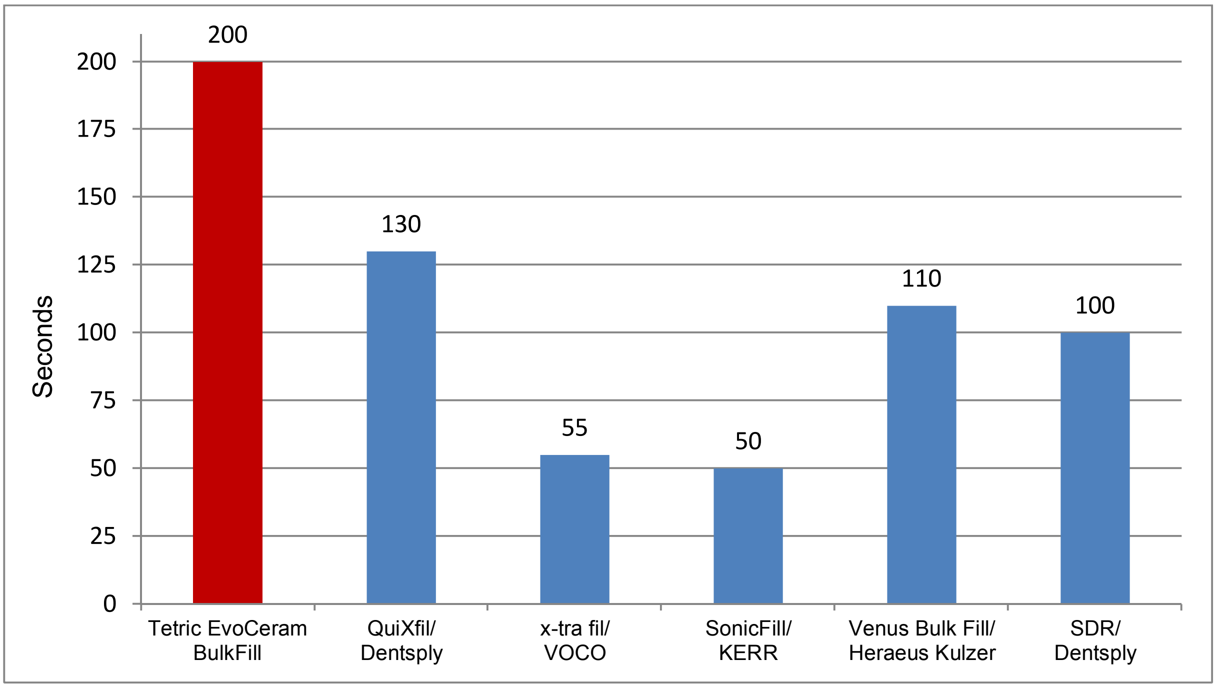


Fig. 21: Insensitivity to ambient light/working time of various bulk fill composites determined according to ISO 4049. (*R&D Ivoclar Vivadent AG, Schaan, July 2011)*

4.3 Polymerisation shrinkage

Minimising the shrinkage stress is particularly important in a material that is applied in increments of up to 4 mm. Tetric EvoCeram Bulk Fill therefore contains a shrinkage stress reliever with a low modulus of elasticity. It acts like a microscopic spring, attenuating the forces generated during shrinkage. Reduced polymerisation shrinkage should translate as lower volumetric shrinkage, improved marginal integrity and reduced shrinkage stress force over the composite surface/on the adhesive bond. Flowable composites usually exhibit higher shrinkage due to a lower filler content, thus for comparison purposes Tetric EvoCeram Bulk Fill is compared to x-tra fil/VOCO and SonicFill/KERR (products which may be sculpted) in figure 22. When compared to flowable bulk fill products the volumetric shrinkage of Tetric EvoCeram Bulk Fill is comparatively lower.

4.3.1 Volumetric shrinkage

Shrinkage test via mercury dilatometer

The polymerisation shrinkage of various composites was tested. The shrinkage of the sculptable bulk fill products Tetric EvoCeram Bulk Fill, Sonic Fill, QuiXfil and x-tra fil are shown below. The percentage of volumetric shrinkage after 1 hour was measured with a mercury dilatometer. The volumetric shrinkage of Tetric EvoCeram Bulk Fill is similar to that of other sculptable bulk fill composite materials. A 4mm increment demonstrated volumetric shrinkage of just 1.96%

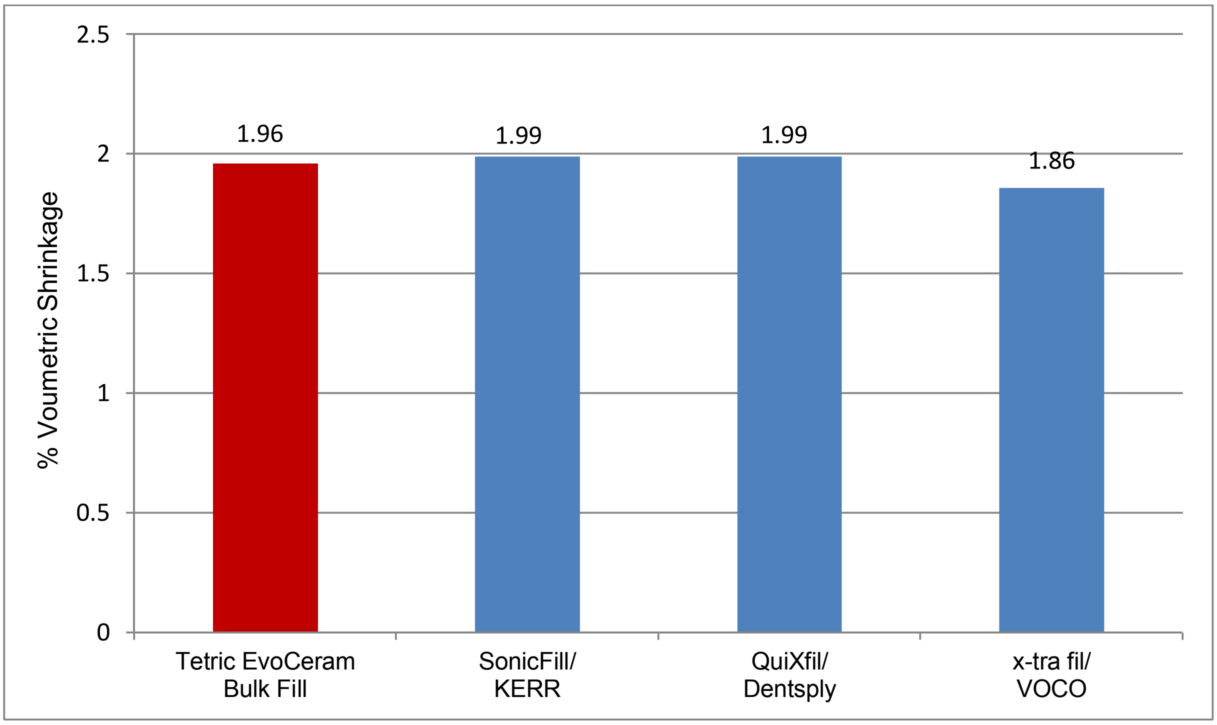


Fig. 22 : Comparison of polymerisation shrinkage of four sculptable bulk fill composites. *(K. Vogel, Abstract 858, AADR Poster, Florida 2012)* [22]

Comparative shrinkage measurements of different dental composites. Dr C. Koplin, Fraunhofer Institut für Werkstoffmechanik IWM Bericht V351/2011

In an external study, the polymerisation shrinkage was also measured via the buoyancy technique, using free-floating test samples in silicone oil.

Method

For this purpose, the materials were tested in a defined quantity and shape. Four bulk fill products were tested: Tetric EvoCeram Bulk Fill, SDR/Dentsply, Venus Bulk Fill/Heraeus and SonicFill/KERR. Five measurements were carried out for each material and each measurement was carried out over a period of 60 minutes at room temperature.

Results

At the beginning of the polymerisation process, an expansion in volume is observed. This is due to the rise in temperature at the onset of the exothermic polymerisation reaction as well as the exposure to light during photoactivation. The exponential decrease in volume comes to a virtual standstill after 10 minutes and after 60 minutes the final shrinkage value can be determined.

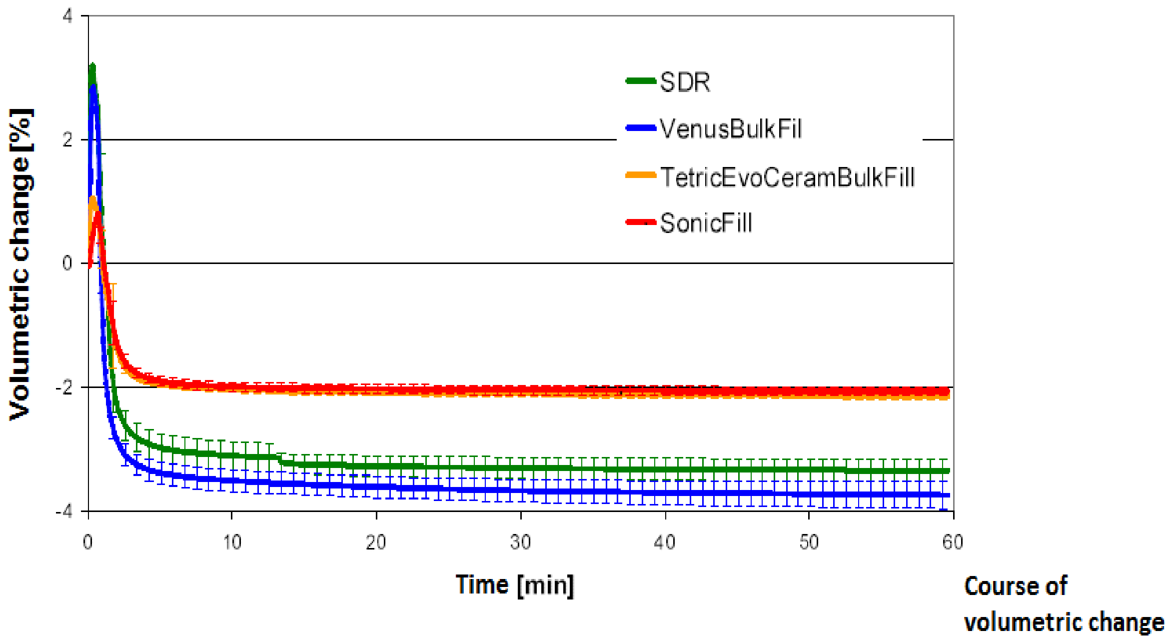


Fig. 23: Course of volumetric change over a period of 60 minutes in various composites. (*Dr C. Koplin, Fraunhofer Institut für Werkstoffmechanik IWM, Freiburg, Germany, 2011)*

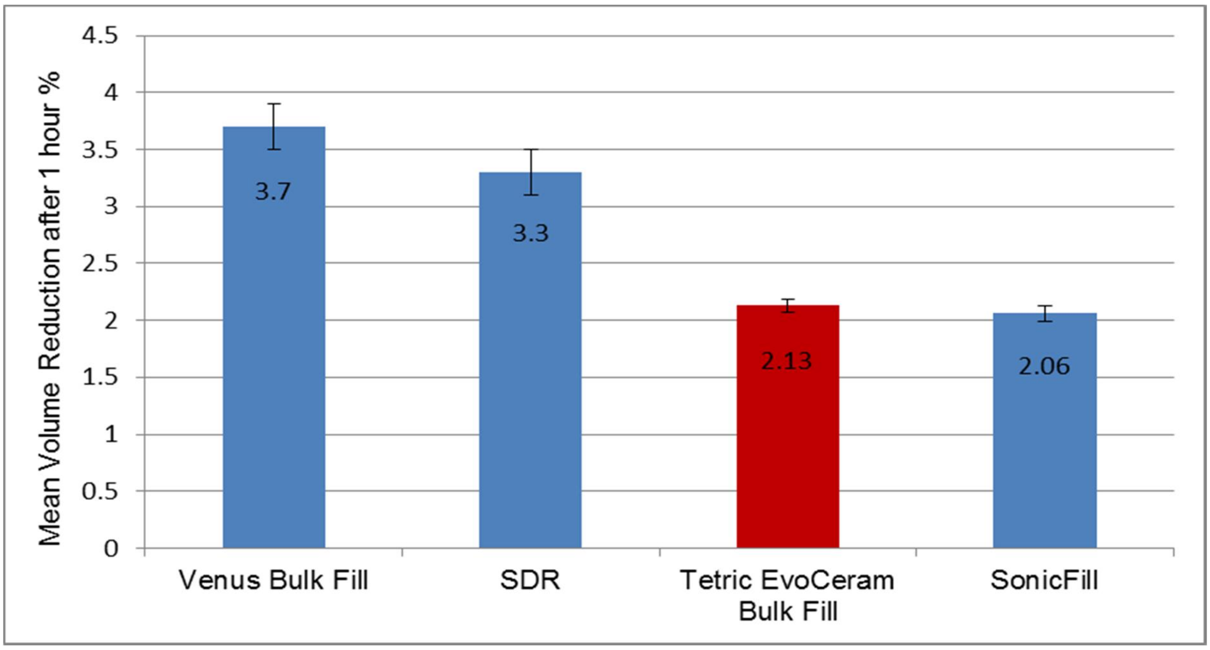


Fig. 24: Mean percentage of volumetric shrinkage after 60 minutes of different composites. *(Dr C. Koplin, Fraunhofer Institut für Werkstoffmechanik IWM, Freiburg, Germany, 2011)*

As expected, the two medium-viscosity (sculptable) composite materials Tetric EvoCeram Bulk Fill and SonicFill/KERR exhibited lower shrinkage than the two flowable bulk fill materials Venus Bulk Fill/Heraeus Kulzer and SDR/Dentsply.

Conclusion

The shrinkage values of both medium-viscosity and flowable materials were within the standard order of magnitude associated with these types of products.

4.3.2 Shrinkage force and stress

The shrinkage stress values of a range of materials were measured in various layer thicknesses. Composites are fixed to the tooth structure with adhesive and cannot shrink freely during the shrinkage process. The force that builds up during shrinkage puts a strain on the adhesive bond. This shrinkage force was examined. The measurements were carried out by means of a Bioman Shrinkage Stress measuring device (light exposure with Bluephase, HIP, for 10 s; shrinkage force measurements over a period of 30 min).

The results show that Tetric EvoCeram Bulk Fill exhibits less shrinkage stress in both 2 mm and 4 mm layers than the universal bulk fill materials SonicFill/KERR and x-tra fil/VOCO, when applied in comparable thicknesses. The test also revealed that the shrinkage stresses measured in the 4 mm layers were not substantially higher than those of the 2 mm layers.

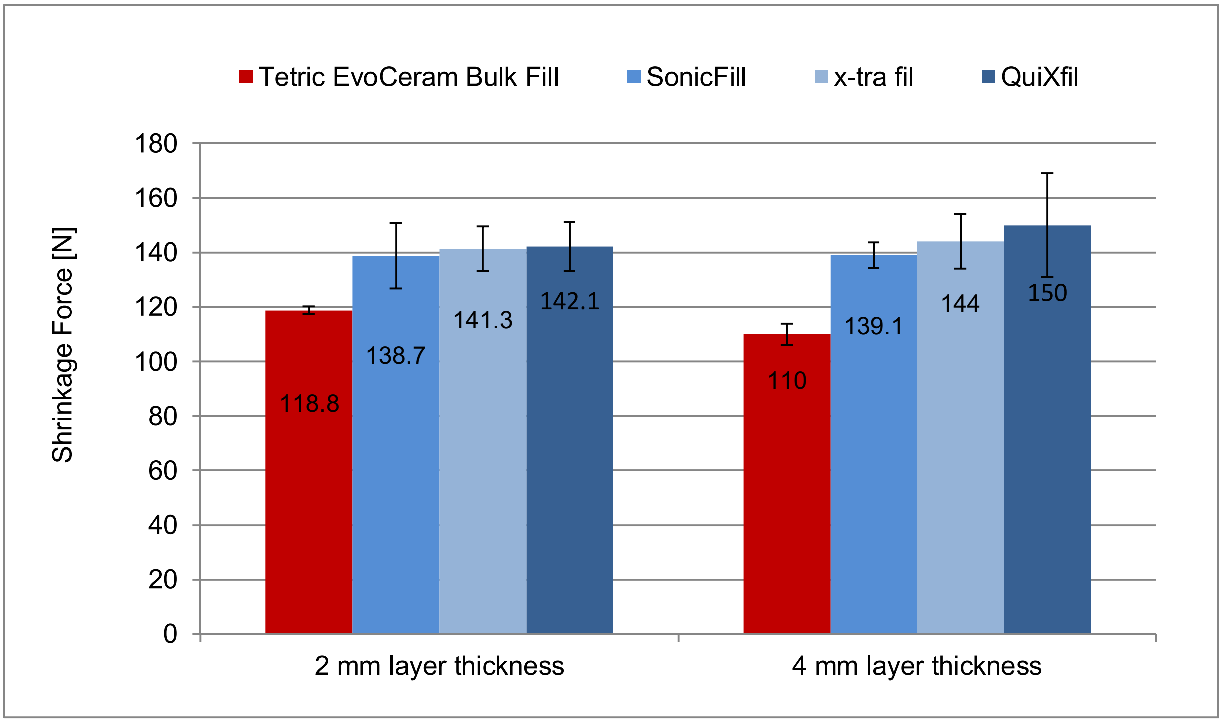


Fig. 25: Shrinkage stresses of various sculptable bulk fill materials measured in 2mm and 4mm layer thicknesses. *(K. Vogel, Abstract 858, AADR Poster, Florida 2012)* [22]

Furthermore, tests showed that the shrinkage force exhibited by a 4 mm increment of Tetric EvoCeram Bulk Fill was lower than that of 2 mm increments of other products.

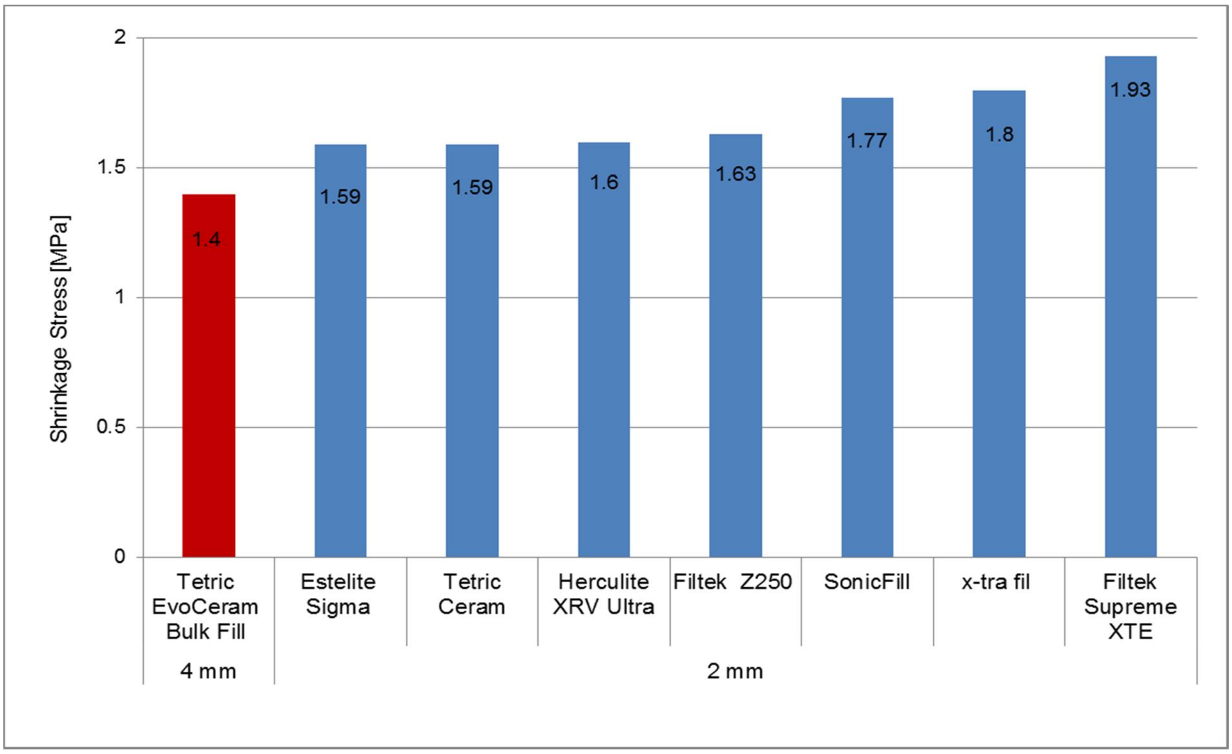


Fig. 26: Shrinkage stress occurring in Tetric EvoCeram Bulk Fill in a layer thickness of 4 mm compared to the shrinkage stresses of other composites in a layer thicknesses of 2 mm. Measurement according to Watts. (*R&D Ivoclar Vivadent, February 2013)*

Characterization of the polymerization contraction stress of a new dental composite, in comparison to four other competitive products. Final Report. Dr J Ferracane. Department of Biomaterials and Biomechanics, OHSU School of Dentistry, Portland, Ohio, USA. (November 2011)

Ferracane et al aimed to compare the shrinkage or contraction stress in five dental composites.

Method

Stress measurements were made according to Watts.[17] The Bioman shrinkage stress instrument was designed and constructed at the University of Manchester. The system is based on a cantilever load-cell. The compliant end holds a circular steel rod vertically and perpendicularly to the load-cell axis. The counterface is a removable ridging fused quartz plate held in a special clamp during measurement. The lower end of the steel rod is sand blasted and in contrast to the original methodology the surface of the glass plate opposing the steel rod is just silanated without sand-blasting. The composite was introduced between the plate and vertical rod to form an uncured specimen disc of 5 mm diameter and 0.8 mm thickness (which represents a bonded to non-bonded surface area ratio i.e. a cavity configuration/C-factor of around 3). The composite is cured from below by a light curing unit for 40 s. The load signal from the cantilever cell is amplified and acquired by a standard computer. The load (N) is divided by the disc area to obtain stress values (MPa). Measurements were taken 10 minutes after curing. Five samples per composite were tested.

Results

The mean stress values were calculated from the five raw stress values per material.

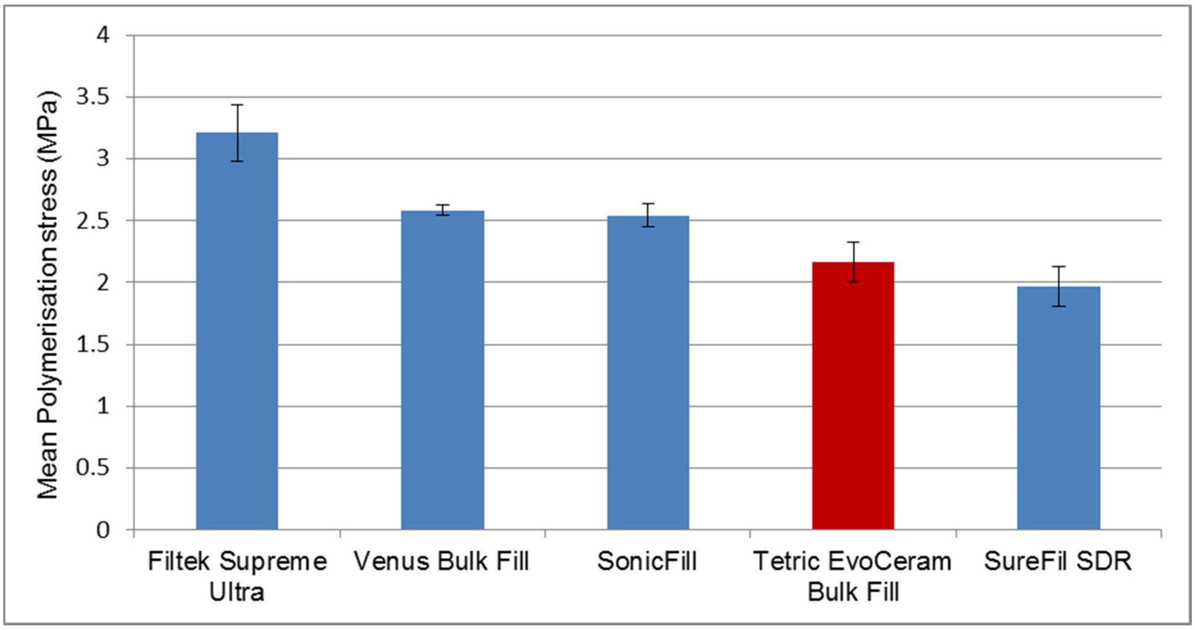


Fig. 27: Mean polymerisation/shrinkage stress values for five different composites. (*Ferracane November 2011)*

Conclusion

Tetric EvoCeram Bulk Fill exhibited significantly less stress than each of the other composites except SureFil SDR with which it was more or less equivalent.

From both internal and external investigations, it can be inferred that Tetric EvoCeram Bulk Fill is clinically acceptable and marginal quality should not be compromised. Intermediate polymerisation of 2mm increments is not necessary and the entire cavity can be filled in one go/in 4 mm increments and bulk cured. [9]

4.3.3 Marginal seal

A comparison was made of marginal integrity using both the 2 mm and 4 mm increment techniques using scanning electron microscopy. Two 4 mm deep MO cavities were prepared on either side of one molar. The cavities were both pre-treated with ExciTE F adhesive. One cavity was conventionally filled with two 2 mm increments of Tetric EvoCeram and involved an intermediate and final polymerisation step with Bluephase Style. The other cavity was filled with a single 4 mm increment and cured once with Bluephase Style. The tooth was then subjected to thermocycling (10,000 cycles) whereupon the margins of both fillings were examined. When restorations show 75% or more intact margin at 200x magnification the marginal quality is considered to be excellent. This applied to both materials. Both restorations showed comparable margin results. The Tetric EvoCeram restoration exhibited 79.9% intact margins whereas Tetric EvoCeram Bulk Fill exhibited 79.2% intact margins.[9]

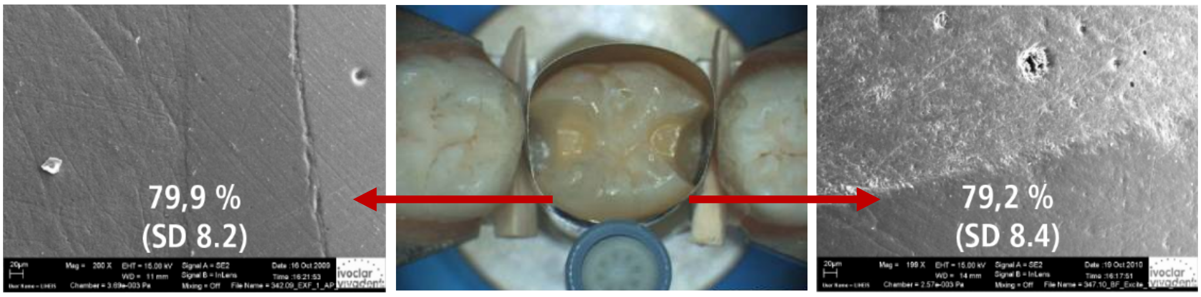


Fig. 28a-c: Marginal analysis of Tetric EvoCeram (SEM left) and Tetric EvoCeram Bulk Fill (SEM right)

Microleakage of five composites. Burgess J, Cakir D. University of Alabama at Birmingham. USA. (2012)

Burgess et al measured the microleakage at both dentin and enamel margins of Tetric EvoCeram Bulk Fill and four other composite resins.

Method

Human intact molars were selected. Two cavities were prepared per molar – one occlusal class I to measure enamel leakage and one MO or DO class II to measure dentin leakage. All cavities were etched with 37% phosphoric acid, bonded with Excite F and cured with Bluephase 20i. Five composite materials were investigated: Tetric EvoCeram Bulk Fill, Venus/Heraeus Kulzer, SureFil SDR/Dentsply, SonicFill/KERR and TPH3/Dentsply. 15 molar specimens (2 cavities per tooth) were prepared for each composite (5 groups thus n=75 molars and n=150 fillings. All composite restorations were applied in 4mm “bulk” increments apart from TPH3 which was applied in two 2mm increments. Leakage was measured using 2% methylene blue dye penetration using a digital microscope at 30x magnification.

Results
TPH3 was applied in standard 2 mm increments for comparison. There were no significant differences in enamel or dentin marginal leakage between any of the composites.

Conclusion
There was no increase in marginal leakage associated with the bulk technique.

A laboratory evaluation of the marginal quality of "Bulk Fill" restorative systems. Final Report. Dr M. Latta, Creighton University School of Dentistry, Omaha, Nebraska, USA. (April 2012)
The nature of gaps at the composite/tooth interface can be significantly influenced by the adhesive system. Latta investigated the marginal quality of 3 different companies' composite systems: Tetric EvoCeram with Excite F, SureFil SDR with Prime & Bond NT/Dentsply and TPH3 with Prime & Bond NT/Dentsply.

Method
Intact human molars were prepared with a slot preparation on the mesial and distal surfaces – 4 mm wide bucco-lingually, 4 mm deep and 2 mm in an axial direction. Six restorations were evaluated per system. Dental adhesives were applied, a metal matrix placed and cavities were filled in bulk with the selected restorative material. Proximal margins were finished with an Enhance disc and polished with SofFlex flexible discs. After 24 hours water storage polyvinyl impressions were made. Teeth were thermocycled for 2500 cycles between water baths of 5 °C and 55 °C and restorations were re-impressed. Teeth were sectioned mesio-distally and polished to a 2400 grit surface. Sections were conditioned in 37% phosphoric acid for 1 minute and these sections were then impressed. Impressions were sputter coated and evaluated under SEM. Marginal integrity between the resin composite, the enamel and the dentin was expressed as a percentage of the entire margin length. The percentage of intact or gap-free margin was calculated as marginal integrity.

Results

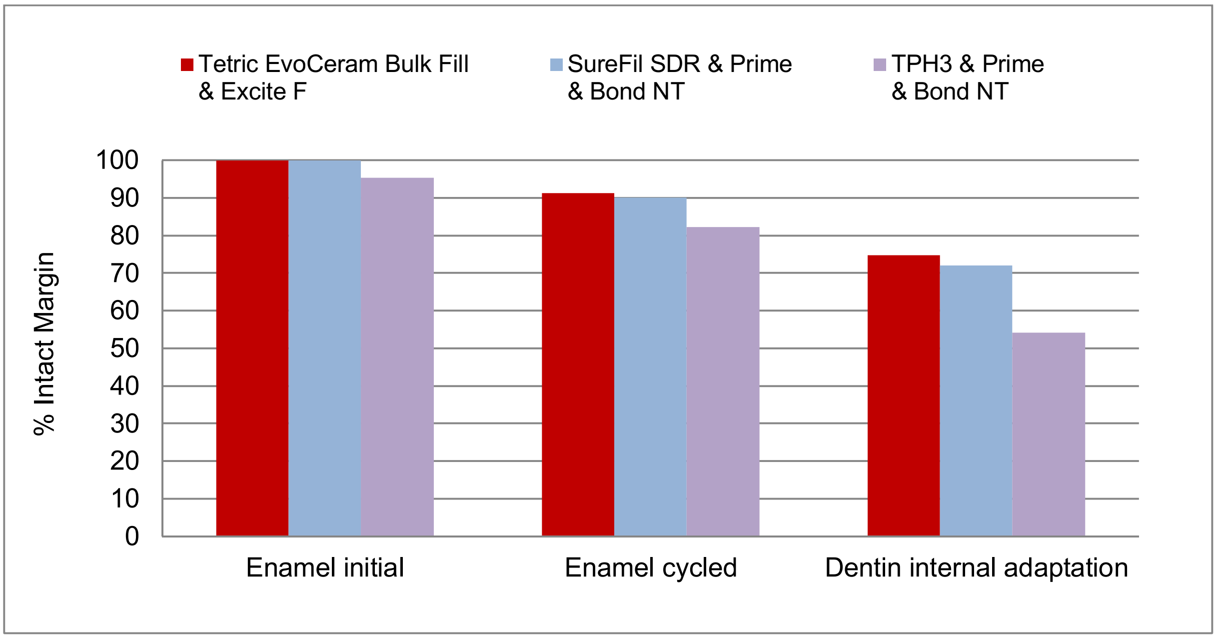


Fig. 29: Percentage of intact margins in enamel (initial and after thermocycling) and dentin in three different composite materials. *(M. Latta, Creighton University School of Dentistry, Nebraska, USA)*

Before thermocycling Tetric EvoCeram Bulk Fill and SureFil SDH both exhibited 100% marginal integrity in enamel margins. After thermocycling this had dropped to 91.3% and 90.1% respectively and 74.8% and 72.1% in dentin.

Conclusion
Tetric EvoCeram Bulk Fill showed higher results at all stages and locations. There was no statistically significant difference between Tetric EvoCeram Bulk Fill and SureFil SDR in this study but both differed significantly from TPH3 ($p < 0.05$). Both bulk fill products showed better marginal integrity in both enamel and dentin than the conventional composite TPH3 with Prime & Bond.

4.4 Wear

Ivoclar Vivadent uses a Willytec chewing simulator to measure the wear resistance of restorative materials. The aim is to emulate mastication processes using a standardised procedure in order to obtain results that can be compared with each other. To achieve this, standardised ceramic antagonists (IPS Empress) are employed and plane test samples are subjected to 120,000 masticatory cycles, with a force of 50 N and a sliding movement of 0.7 mm. The vertical substance loss is measured by means of a 3D laser scanner. A vertical loss of 200 µm is considered low and a loss ranging between 200 – 300 µm is considered medium.

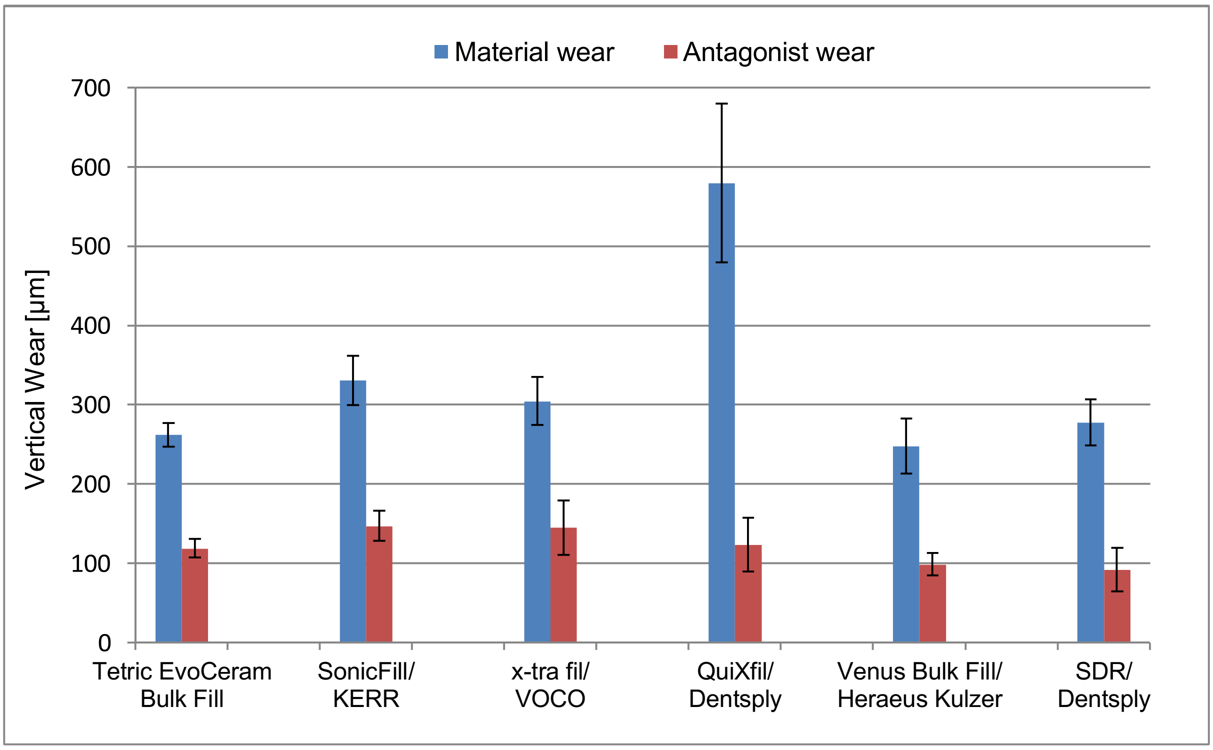


Fig. 30: Mean vertical wear of restorative materials and their antagonists *(R&D Ivoclar Vivadent, 2011)*

In terms of material wear, the highest results were found in test samples of QuixFil. SDR, Venus Bulk Fill and Tetric EvoCeram Bulk exhibited low and comparable wear, whereas Quixfil and SonicFill showed significantly higher wear. With regard to antagonist wear, there was less variation but significantly higher wear was recorded for SonicFill and X-tra fil test samples.

4.5 Polishability

Polishing represents a critical step in direct restorative treatment. A pleasing surface gloss is decisive for the clinical success and aesthetic appearance of a composite restoration.

Restoration surfaces that are too matte in relation to the surrounding tooth structure are unaesthetic and rough surfaces are conducive to staining and plaque accretion. Special attention was therefore given to achieving advantageous polishing properties in the development of Tetric EvoCeram Bulk Fill.

For the experiment below, eight specimens of each material were prepared according to manufacturer instructions. Six bulk fill composites were tested. The specimens were roughened with sand paper (320 grit) to achieve a defined initial surface roughness. The specimens were then stored in a dry-storage area at 37 °C for 24 hours, whereupon their gloss was measured with a Novo-Curve Glossmeter and surface roughness was determined with an FRT MicroProf measuring device.

The specimens were polished using a single-step OptraPol Next Generation polisher at a pressure of 2 N at 10,000 rpm under water cooling. Specimens were polished for 30 seconds in total, with the surface gloss measured at intervals of 10 s. The reference material was black glass with a gloss index value of 92.6.

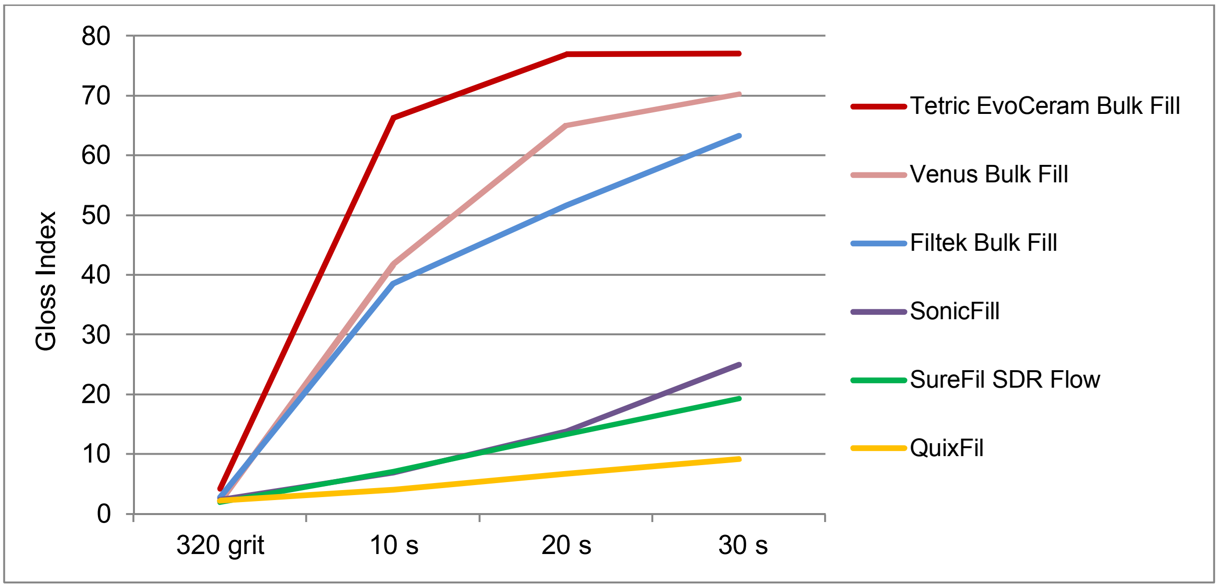


Fig. 31: Mean surface gloss of various bulk fill composite materials compared to Tetric EvoCeram Bulk Fill after polishing with OptraPol Next Generation in relation to polishing time. (*Preclinic R&D Ivoclar Vivadent, Schaan, August, 2011)*

The test samples made of Tetric EvoCeram Bulk Fill showed a statistically significant, higher surface gloss than the other materials investigated at all stages of the 30-second polishing time when polished with the OptraPol Next Generation polishing system (ANOVA, $p<0.05$).

In a further test surface roughness was determined after 10, 20 and 30 seconds of polishing. The mean surface roughness values are shown in the diagram below. The lower the surface roughness value, the better the polishability of the material. A mean surface roughness of <0.1 µm indicates excellent polishability, <0.2 µm suggests good polishability, a value between 0.2 - 0.4 µm corresponds to a medium polishability and >0.4 µm means poor polishability. Tetric EvoCeram Bulk Fill exhibited excellent polishability and after 30 seconds polishing there was no significant difference in surface roughness between Tetric EvoCeram Bulk Fill, Venus Bulk Fill and Filtek Bulk Fill.

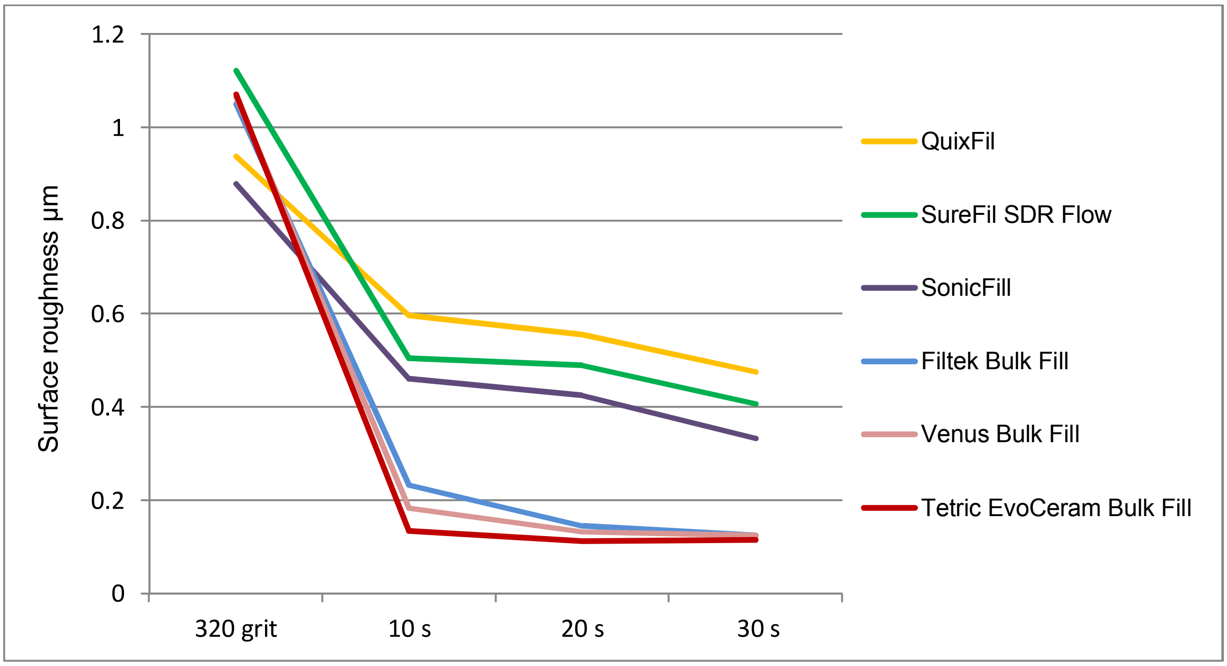


Fig. 32: Mean surface roughness of various composite materials compared to Tetric EvoCeram Bulk Fill after polishing with OptraPol Next Generation for a polishing time of 30 s. (*R&D Ivoclar Vivadent, Schaan, 2011)*

5. Clinical Investigations / In Vivo

Tetric EvoCeram Bulk Fill. The Dental Advisor, Vol. 29, Nr 5, June 2012, Dental Consultants Inc.
Tetric EvoCeram Bulk Fill achieved a 5 star (97%) rating as the Editors' choice in a Dental Advisor review. It was clinically tested by 31 consultants who placed 746 restorations with Tetric EvoCeram Bulk Fill according to manufacturer instructions. The product was described as having very good handling properties for posterior use, with the 4 mm depth allowing filling of most cavities with one layer so shortening the application time. It adapted well to cavity walls and was easily "sculptable". The three shades were adequate for posterior use and their translucency blended naturally with the enamel. In cases of deeply stained dentin it was mentioned that the colour could show through the composite if not blocked out with an opaque liner. Radiopacity was very good and 61% of consultants rated Tetric EvoCeram Bulk Fill as better than their current bulk fill product and 32% as equivalent. 84% said they would switch to Tetric EvoCeram Bulk Fill and 94% would recommend it.

Internal clinical investigation of Tetric EvoCeram Bulk Fill: Dr A. Peschke, Internal Clinic, R&D, Ivoclar Vivadent, Schaan, Liechtenstein. (2012)
Tetric EvoCeram Bulk Fill was tested in the internal clinic alongside an experimental adhesive.

Method
35 posterior restorations (11 Class I and 24 Class II) were placed by 3 dentists: (dentist 1: n=12, dentist 2: n=11, dentist 3: n=12), together with an experimental etch and rinse adhesive. All fillings were placed using a rubber dam. Two restorations were placed due to primary caries and the remaining 33 involved replacing fillings due to secondary caries. The average cavity depth was 4 mm. The mean cavity dimensions are shown in the following table:

Cavity Size	Cavity Width (mm)	Cavity Width (% of inter-cuspal distance)	Central Occlusal Depth (mm)	Depth of Mesial Box (mm)	Depth of Distal Box (mm)
Mean	4.8	77 %	4	5.2	4.5
SD (±)	1.7	16 %	1.2	1.0	1.7
Max.	10	100 %	6	7.0	7.0

Table 5: Average cavity characteristics with standard deviations. (*Internal clinic R&D, Ivoclar Vivadent 2012)*

In 29 cases the shade IVA was used, in 3 cases, IVB was used and IVW was utilised for 3 restorations. Polymerisation was carried out with Bluephase for 10 seconds per increment.

Baseline results were obtained after approximately one week. Subsequent recalls are planned in 12-month intervals. FDI-criteria are/will be used for analysis.[18,19] Analysis of the restorative margins was carried out using a semi-quantitative clinical evaluation method (percentage of total margin).

Results
The baseline results are shown below:

FDI Criteria/ FDI Evaluation	Excellent	Good	Sufficient	Unsatisfactory (but reparable)	Poor/unacceptable (replacement necessary)
	Number (% of all fillings)				
Postoperative sensitivity	35 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Anatomical form	34 (97%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)
Surface, shine, pores	27 (77%)	2 (6%)	6 (17%)	0 (0%)	0 (0%)
Aesthetic appearance	25 (71%)	10 (29%)	0 (0%)	0 (0%)	0 (0%)
Surface discoloration	35 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Patient satisfaction	34 (97%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)
Material fracture	35 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Tooth integrity	34 (97%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)
Approximal contacts	33 (94%)	1 (3%)	1 (3%)	0 (0%)	0 (0%)
	% of total margin				
Marginal discoloration	99.9 %	0.1%	0%	0%	0%
Marginal defects	99.1%	0.9%	0%	0%	0%
Insufficient material	99.9 %	0.1%	0%	0%	0%

Table 6: FDI criteria and evaluation of baseline characterisics of restorations (n=35*). (Internal clinic, R&D, Ivoclar Vivadent 2012)*

Conclusion
It was possible to place highly aesthetic posterior restorations with Tetric EvoCeram Bulk Fill. There were no postoperative complaints after 1 week in situ. Anatomical form, aesthetic appearance, surface discoloration, material fracture, tooth integrity and patient satisfaction were classified excellent or good in all cases at baseline.

6. Biocompatibility

To minimise the risks related to biocompatibility as far as possible from the outset, care is taken to ensure that mainly raw materials that have been used in dental composite materials for many years and have been proven *in vivo* to be safe, are used in the development of new materials. Tetric EvoCeram Bulk Fill is based closely on the well-established product Tetric EvoCeram and its toxicological properties can be evaluated using data from this and other well-established composites and their ingredients.

6.1 Cytotoxicity

Samples of Tetric EvoCeram Bulk Fill were extracted in RPMI 1640 medium according to ISO 10993-12. Subsequently, L929 cells were brought into contact with this extract for 24 hours. The vitality of these cells was measured after 24 hours with the help of tetrazolium dye (XTT). Extracts of Tetric EvoCeram Bulk Fill did not show any relevant effects on the cell cultures. Tetric EvoCeram Bulk Fill was therefore found to be non-cytotoxic.

6.2 Mutagenicity

Extracts of material samples were examined in a reverse mutation test (Ames test). None of these tests indicated any mutagenic activity. Ivocerin® was also subjected to extensive testing and showed no signs of mutagenic activity.

6.3 Irritation and sensitisation

Like virtually all light-curing dental materials, Tetric EvoCeram Bulk Fill contains methacrylates and dimethacrylates. These materials (notably in their uncured state), may have an irritating effect and may cause sensitisation. This can lead to allergic reactions, such as contact dermatitis. Allergic reactions are very rare in patients but occur more frequently among dental staff, who handle uncured composite material on a daily basis. Such reactions can be minimised/avoided by clean working conditions and avoiding skin contact with uncured material. It should be noted that commercially available medical gloves do not provide effective protection against the sensitising effects of methacrylates.

Tetric EvoCeram Bulk Fill must not be used in patients who are known to be allergic to any of its constituents.

6.4 Conclusion

On the basis of the data available, it can be concluded that Tetric EvoCeram Bulk Fill poses no health hazard if used correctly. To ensure correct use, the notes and directions in the *Instructions for Use* must be observed and followed.

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