3s PowerCure

Scientific
Documentation

Efficient
Esthetics

ivoclar vivadent
passion vision innovation

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1. Advances in direct restoration

As direct dental restorative materials have advanced, so has the technology to cure these materials. Dental composites have improved in quality, esthetics and efficiency, adhesives have advanced in terms of bond strength, reduced working steps, universality and efficiency; curing lights have become more powerful, more ergonomic and more user-friendly. This Scientific Documentation describes the 3s PowerCure-System which takes the state of the art in adhesives, direct composites and light curing to create one coordinated system for efficient esthetics.

1.1 State of the art in adhesives

Adhesive dentistry has undergone remarkable and constant progress over recent decades - and has undoubtedly co-revolutionized restorative dental practice.[1] Adhesives became necessary in direct restorative dentistry with the advent of dental composites, heralding a new minimally invasive era, as the cavity to be filled, had only to be as large as the demineralized tissue to be removed. This of course, could only be achieved with the development of clinically reliable enamel/dentin adhesives.

Adhesive classification and development

Adhesive development went through several logical technological steps, culminating in the various generations, working steps and types of dental adhesive known today. Classification by generation is not unproblematic due to historical and technical inconsistences.[2] Adhesives are however often referred to by dental manufacturers in terms of generation – largely based on their chronological introduction to the market. Alternatively, modern adhesives (3rd generation onwards) are often classified according to the etching technique i.e. Etch & Rinse or Self-Etch and thereafter according to the number of working steps involved. Table 1 attempts to combine both methods of classification as an overview.

Generation	Developed	Mechanism / Steps		Description
1	1960s	**No Longer in Use**		Enamel etch only – poor adhesion
2	1970s			Enamel etch only – improved adhesion
3	1980s/1990s	**Etch & Rinse**	**Selective-Etch/ Multi-Step**	Selective enamel etch/etch-and-rinse with H_3PO_4. Dentin conditioned with primer to modify or remove smear layer
4	1990s		**Total-Etch/ Multi-/3-Step**	Total-etch/etch-and-rinse: separate primer and adhesive
5	Mid 1990s		**Total-Etch/ 2-Step**	Total-etch/etch-and-rinse: combined primer and adhesive
6	Late 1990s	**Self-Etch**	**Self-Etch/ 2-Step**	Self-etch: etch and primer combined then hydrophobic bonding i.e. self-etch/multi-component
7	2000 +		**Self-Etch/ 1-Step**	Self-etch: etch, primer and adhesive combined i.e. self-etch/single component
Universal	2011 +	**All-Etch**	**Total-/Self-/Selective-Etch/ 1 or 2-Step**	Total or selective etch procedure followed by universal adhesive or universal adhesive only in self-etch mode

Table 1: Classification of adhesives according to generation, etch technique and number of clinical steps.

Universal adhesives
Adhesive development has provided dentists with products that reduce inventory, are more efficient and easier to apply. Universal adhesives such as Adhese Universal, which appeared on the market in 2011 represent the current state of the art in dental bonding. They provide one product that deals simultaneously with the many steps (enamel conditioning, dentin conditioning, wetting and bonding) necessary to achieve a sound bond – by combining an acidic primer and an adhesive resin. They are indicated for both direct and indirect procedures, and (most) can be used with any etching technique depending on the clinical situation and preference of the dentist.

1.2 State of the art in direct composites

Dental composites have developed hand in hand with dental adhesives. Appearing in the 1960s, [3] they were initially mainly used in the anterior region, where amalgam fillings were deemed unaesthetic but in the 1990s began to substitute amalgam as a universal filling material. The composite success story was driven, not only by patient demand for increasingly esthetic filling materials but by continued industry-led product development and improvement with regard to the physical, esthetic and handling qualities of adhesives and composites.

Direct composite development
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.[3] At the time, only chemically-cured two-component resin-based materials were available. With the advent of photo-polymerization, UV-cured systems were introduced[4] and in the late 1970s, the first report on a dental filling material that could be cured with visible blue light was published.[5] Direct composites were historically somewhat limited with regard to large posterior restorations due to accelerated wear and polymerization 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. Modern direct composites have long been applied according to standard dental teaching that recommends a maximum layer thickness of 2mm.[6,7] This was in order to minimize 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] The newer bulk-fill composites designed for filling large posterior restorations in one layer (depending on the depth of the restoration) represent the latest development in direct-composite dentistry and a paradigm shift away from the traditional 2 mm increment system. According to a 2018 survey of ACE panel-member dentists in the USA, 26% of their posterior restorations are now bulk fill restorations compared to 70% incremental. [9]

Bulk Fill composites

All bulk fill composites need to exhibit greater depth of cure than traditional composites, plus low shrinkage stress, good marginal integrity, resistance to chewing forces, adequate working time in ambient light, adequate radiopacity, good polishing properties and aesthetics. The sculptable (non-flowable) materials can be applied in one increment or more (depending on the depth of the cavity) and moulded and sculpted to mimic the natural tooth topography. The flowable bulk fill materials are unsuitable for single-layer fillings, as they cannot be sculpted at the surface. These are topped with a sculptable conventional or coordinated bulk fill composite in order to model cusps and create life-like morphology. The sculptable and flowable bulk fill composites Tetric EvoCeram Bulk Fill and Tetric EvoFlow Bulk Fill could be realized due to the incorporation of a new, highly reactive germanium-based photoinitiator Ivocerin. Like Universal Adhesives, Bulk Fill composites were a further step in the direction of efficient esthetics in dentistry.

1.3 State of the art in light curing

As dental restorative materials have advanced, so has the technology to cure these materials. The first commercial dental curing light using UV-light was developed in the 1970s. Dr Bassoiuny of the Turner School of Dentistry in Manchester, UK placed the first visible-light cured composite in 1976. The optimizing of a visible-light curing photoinitiator system was key and involved using camphorquinone plus a tertiary amine co-initiator. This initiator combination remains standard to this day and photopolymerization in general, is absolutely integral to modern dentistry. The success and longevity of light-activated materials is directly related to the efficacy of the light curing process. Light-emitting diode (LED) curing lights now dominate the dental market, having overtaken halogen, plasma arc curing (PAC) lights and laser lights. LEDs emitting blue light, were introduced to dentistry in the mid-90s with the first commercially available light arriving in 2000. Far more efficient than previous light sources, they are light-weight and can be battery powered for easy portability and ease of use.[10] Most produce a relatively narrow spectrum of light in the 400 to 500 nm range (with a peak at around 460 nm). LED curing lights have become increasingly popular and several generations co-exist. They are available in many variations: large or small, corded or cordless, polywave or monowave.

Generations of LED light

There are currently three generations of LED light to speak of. The first generation of LEDs featured a relatively low light output of approximately 400 mW/cm^2, with the second generation reaching approximately 1000 mW/cm^2. The 1st and 2nd generations of LED lights using just one type of LED (single peak / monowave technology) were unable to cure certain composite materials due to wavelength emissions incompatible with the photoinitiator wavelength curing ranges. In order to be cured successfully, the composites had to contain the light initiator camphorquinone, whilst other initiator systems such as acyl phosphine oxide e.g. Lucirin TPO were contraindicated due to wavelength “incompatibility”. This was a considerable drawback in contrast to halogen lamps, which emitted a broader spectrum of light and were therefore able to cure composites containing all types of initiator. The newer 3rd generation of LED light often features a higher light output and circumvents the wavelength-incompatibility problem by utilizing dual/multi peak i.e. polywave technology. Though not technically correct - the term broad-band technology is also sometimes applied to this group of LED units.[11] This utilizes different LEDs in one curing light to cover a wider emission spectrum from approximately 385 – 515 nm (i.e. a similar emission spectrum to that of halogen lamps) but with two or more spectral peaks. This enables the polymerization of restorative materials that utilize non-camphorquinone based initiators. Curing units of this generation are therefore usually capable of curing any dental restorative material.[12] Most Bluephase products belong to this generation of lights. The Bluephase G4 and Bluephase PowerCure units with high power and features such as "Polyvision", herald the fourth generation of polywave curing lights.

2. 3s PowerCure-System

The 3s PowerCure-System comprises four coordinated products: the adhesive Adhese Universal, the sculptable and flowable 4mm composites Tetric PowerFill and Tetric PowerFlow and the high power curing light Bluephase PowerCure, capable of curing the adhesive and composites in just 3 seconds.

The 3s PowerCure-System is an open dental system, i.e. each individual product covers a range of standard indications and ways in which it can be used. As a coordinated 3s PowerCure-System however, intended use refers only to the use of these products together - for the direct restoration of permanent posterior (Class I or II) cavities whereby curing can be carried out unhindered from the occlusal aspect. The individual products and their interfaces with each other are described below. For Adhese Universal and Tetric PowerFlow further details can also be obtained from the Adhese Universal Scientific Documentation and the R&D Report No.20 respectively.

2.1 Adhese® Universal

As part of the 3s PowerCure-System, Adhese Universal is a single-component, light-cured adhesive for use with direct posterior restorations (Class I or II), that can be cured from the occlusal aspect.

Fig 1: Adhese Universal VivaPen with new orange stripe design - as part of 3s PowerCure-System

Adhese Universal can be applied using either the Etch & Rinse, Self-Etch or Selective Enamel-Etch technique. The choice of tooth conditioning technique depends on the dentist’s assessment of the clinical situation i.e. which will achieve superior clinical longevity and patient satisfaction.

Fig. 2a-c: Etch & Rinse Selective Enamel-Etch Self-Etch with Adhese Universal

Adhese Universal is then applied to the cavity and rubbed into the surfaces for at least 20 seconds. It is then dispersed with oil/moisture-free compressed air until a thin glossy immobile film-layer results and light cured for 3 seconds using the 3s PowerCure-Mode of the Bluephase PowerCure polymerization unit.

Adhese Universal bonding mechanism

Adhesive systems must establish a bond to both the restoration and the dental hard tissue. Composite restoratives consist of a hydrophobic matrix in which different filler particles are embedded. Teeth are comprised of two very different substrates: enamel and dentin. Enamel is essentially 96% hydroxyapatite, crystalline calcium phosphate, and 4% organic material and water[13] whereas dentin consists of 70% hydroxyapatite, 20% collagen and 10% water.[14] Enamel is thus an essentially dry substrate, whilst dentin is moist, though both can be considered essentially hydrophilic in comparison to restorative materials. Adhesives therefore need to possess both hydrophobic and hydrophilic properties in order to establish a bond to both tooth and restorative substrates. Earlier generations of adhesives achieve(d) bonding via dealing with each bonding step in succession. Syntac a classic example of a 3rd/4th generation adhesive is useful for illustrating this point.

<table>
<tr><th>Working Step</th><th>Purpose</th><th>Syntac
(1990)</th><th>Adhese Universal
(2014)</th></tr>
<tr><td>Enamel conditioning</td><td>Expose retentive etching pattern</td><td>Total Etch
(H_3PO_4)</td><td rowspan="4">Adhese Universal</td></tr>
<tr><td>Dentin conditioning</td><td>Modify smear layer and expose collagen and tubules, infiltration and hydrophilic wetting</td><td>Syntac Primer</td></tr>
<tr><td>Wetting</td><td>Infiltrate collagen with hydrophilic resin. Create transition between hydrophilic substrate and restoration via tag formation</td><td>Syntac Adhesive</td></tr>
<tr><td>Bonding</td><td>Hydrophobic bonding agent to bond to restoration via co-polymerization with restorative material</td><td>Heliobond</td></tr>
</table>

Table 2: Bonding steps and mechanism of action: Syntac and Adhese Universal

The Adhese Universal matrix is based on a combination of monomers of hydrophilic (hydroxyethyl methacrylate/HEMA), hydrophobic (decandiol dimethacrylate/D3MA) and intermediate (bis-GMA) nature. This combination of properties allows Adhese Universal to bridge the gap between the hydrophilic tooth substrate and the hydrophobic resin restorative, under a variety of surface conditions. Its relatively low pH of approx. 2.5 – 3.0 allows for its use as a Self-Etch adhesive.

The water/ethanol solvents and the integrated micro-fillers used in Adhese Universal are also designed to enhance penetration into the dentin tubuli to ensure the formation of a reliable dentin seal by a homogenous adhesive layer with defined resin tags. In addition, the acidic monomers contained in Adhese Universal trigger a coagulation of the proteins in the dentinal fluid - so contributing to the mechanical sealing of the tubuli by helping to prevent fluid movement and thus postoperative sensitivity associated with that movement. A combination of thixotropic silica and carboxylic acid functionalized polymer also facilitates the uniform film-formation of Adhese Universal. During the recommended 20 second scrubbing application, the adhesive flows over, penetrates and covers the dentin uniformly. Diffusion through the smear layer aids mechanical sealing and thus desensitization.

2.2 Tetric® PowerFill

Tetric PowerFill is a light-cured, sculptable, radiopaque, 4mm composite for the direct restoration of posterior teeth. Tetric PowerFill can be cured with light in the wavelength range of 400-500nm and can be applied in layers of up to 4mm. Tetric PowerFill is based on the now well-established sculptable bulk fill composite Tetric EvoCeram Bulk Fill.

As a stand-alone product, Tetric PowerFill is indicated for Class I and II posterior restorations (including the replacement of individual cusps), Class V restorations, reconstructive build-ups and the restoration of deciduous teeth. In these cases, conventional polymerization is carried out with a curing light with power of up to 2000mW/cm^2.

As part of the 3s PowerCure-System, Tetric PowerFill is intended for application after the 3 second curing of Adhese Universal and is only indicated for restorations in the posterior region of permanent dentition (Class I and II – including the replacement of individual cusps) when unhindered light curing from the occlusal aspect is possible.

Fig. 3: Schematic representation of a 3s PowerCure restoration

Each layer of up to 4mm is cured using the Bluephase PowerCure light in 3s PowerCure-Mode. Very deep cavities and cases of caries profunda are contraindicated, as the high power curing mode is unsuitable for areas close to the pulp.

Tetric PowerFill is available in three universal shades: ^{IV}A, ^{IV}B and ^{IV}W. If repairs are necessary, Tetric PowerFill can be applied directly to the polymerized material, however if the restoration was pre-polished it should be roughened using a diamond grinding instrument and wet with Adhese Universal before fresh composite material is applied.

Tetric PowerFill can either be used alone as described above or it can be used in combination with the new flowable composite Tetric PowerFlow. In such cases Tetric PowerFlow is applied in up to 4mm layers then finished with a thin layer of the sculptable Tetric PowerFill for the creation of natural tooth-topography.

Composition development

The possibility to cure 4mm increments still represents an ongoing paradigm shift in dentistry. For years, it was an accepted fact that to create a reliable composite with minimal polymerization 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.[15] Tetric EvoCeram Bulk Fill was a first step in this direction, involving advanced composite-filler technology, a pre-polymer shrinkage stress reliever, a light initiator/polymerization booster (Ivocerin®) and a light sensitivity filter.

Monomer technology

Monomers together with initiators, catalysts and other additives, form the reactive part of a resin-based restorative. Monomers compose the final matrix of the material and usually comprise approximately 12 - 40% of the mass of the final material, depending on the characteristics desired. Dimethacrylate monomers are methacrylates with two polymerizable methacrylate groups.

Tetric PowerFill contains the same three dimethacrylates as Tetric EvoCeram Bulk Fill: Bis-GMA, Bis-EMA and UDMA, plus aromatic dimethacrylate and tricyclodocane dimethanol dimethacrylate.

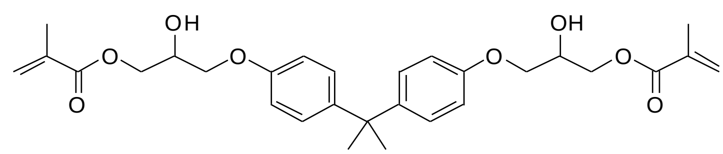
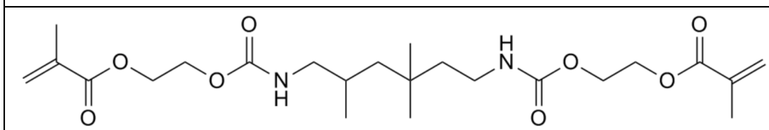
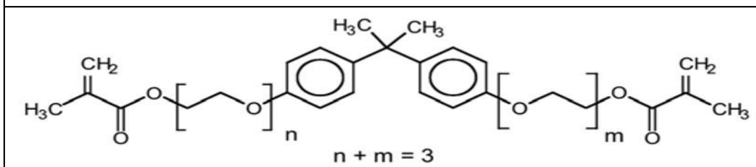
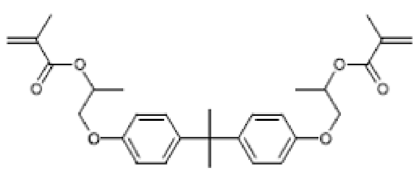
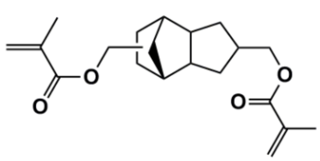
Formula	Monomer
	**Bis-GMA** Bisphenol A-diglycidyl dimethacrylate
	**UDMA** Urethane dimethacrylate
	**Bis-EMA** Ethoxylated bisphenol A dimethacrylate
	**Aromatic dimethacrylate** Propoxylated Bisphenol A dimethacrylate
	**DCP** Tricyclodecane-dimethanol dimethacrylate

Table 3: Table illustrating the structural formulae for the monomers used in Tetric PowerFill

As with all composites, the monomers are converted into a cross-linked polymer matrix during the polymerization process. The organic matrix of Tetric PowerFill accounts for approximately 17% of the mass of the composite.

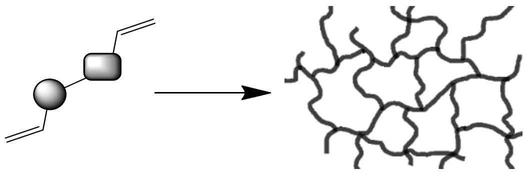


Fig. 4: Schematic representation of cross-linking monomers resulting in a polymer network after curing

BisGMA is the main component of the monomer matrix, it was first synthesized 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. UDMA exhibits moderate viscosity (lower than BisGMA), can therefore be used undiluted and yields strong mechanical properties. It also has no hydroxyl side groups i.e. it is hydrophobic and exhibits low water absorption. DCP is a low-viscosity, difunctional, methacrylate monomer whose cyclic aliphatic structure also ensures strong mechanical properties. Bis-GMA, Bis-EMA and UDMA exhibit low polymerization shrinkage by volume.

Optimal polymerization with AFCT

The composition of Tetric PowerFill was further optimized by including a (β-allyl sulfone) addition fragmentation chain transfer (AFCT) reagent. When Tetric PowerFill is cured in just 3 seconds with the Bluephase PowerCure (3050 mW/cm^2) light, there is by definition, less time to establish "full" polymerization. This drawback is counteracted by the inclusion of the AFCT reagent, which works as a tool for adjusting the thermal and mechanical properties of dimethacrylate networks.[16]

Standard polymerization of cross-linking monomers can be described as radical chain growth polymerization as represented in the schematic drawing below.

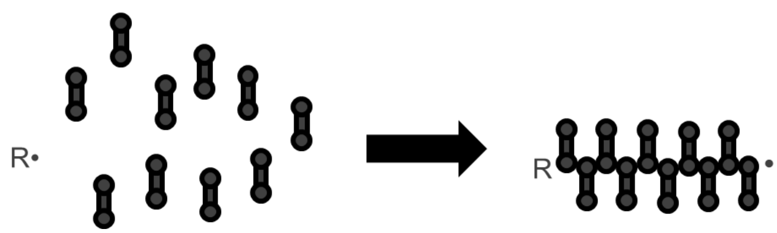


Fig. 5: Methacrylate addition (long chain formation) due to attack of double bonds via radicals

It can lead to materials with an uncontrolled and inhomogeneous network architecture[16]. The fast growth of numerous polymer chains can lead to an early gel point whereby the flexibility and reactivity of the matrix is severely limited. Gorsche et al. showed that the addition of an AFCT reagent to monomer formulations improved the double-bond conversion and resulted in a more homogenous polymer network.

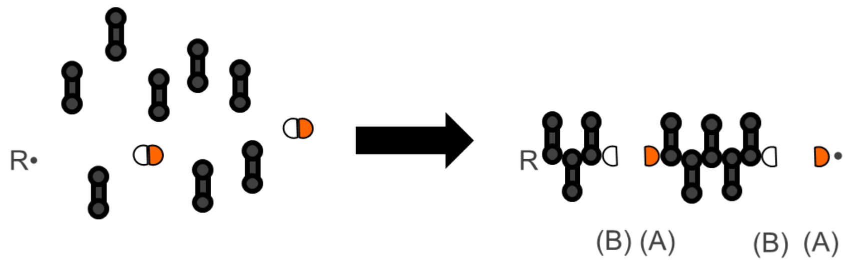


Fig. 6: Methacrylate addition with AFCT (short chain formation) and chain transfer

This is possible because the AFCT reagent pushes an uncontrolled radical chain growth polymerization reaction toward a step growth-like polymerization reaction.[16] During standard polymerization, excited photoinitiators create radicals which attack the double bonds of monomers resulting in methacrylate addition (see figure 5). In Tetric PowerFill, the radicals can potentially attack either a methacrylate double bond of a monomer resulting in methacrylate addition or the double bond of a β-allyl sulfone resulting in chain transfer (see figure 6). In the case of chain transfer, the growing radical chain is terminated by forming an intermediate radical that undergoes fragmentation and forms a sulfonyl radical (A) and a new double bond (B). Essentially successive shorter chain formation is favoured over standard radical long-chain growth, leading to a delayed gel point and a more homogenous network.[16]

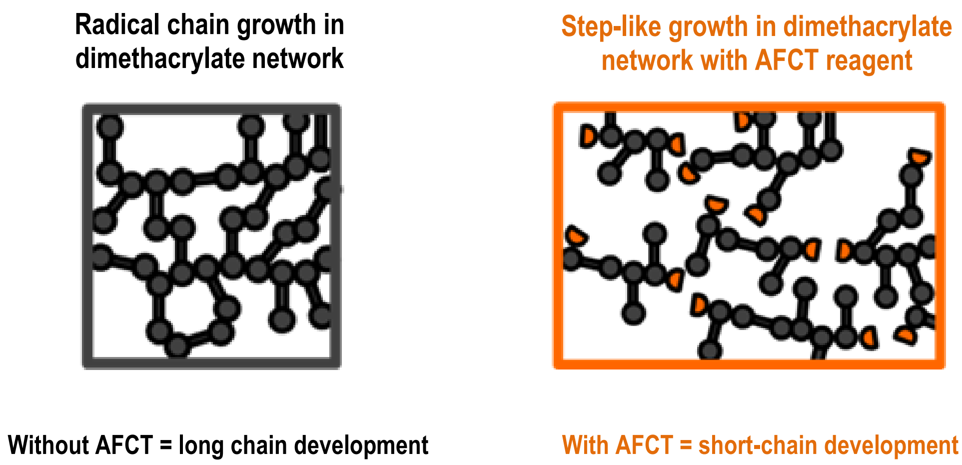


Fig. 7: Simplified models of network growth architecture with and without AFCT.

AFCT reagents therefore allow for a certain amount of control over the radical polymerization process. It is suggested that resultant materials should have reduced shrinkage stress, increased conversion and greater toughness.[17] Such effects are particularly advantageous when shorter polymerization times are in play.

Filler technology

Fillers are responsible for imparting restorative materials with the adequate strength and low wear with which to withstand the stresses and strains of the oral cavity, to achieve acceptable clinical longevity and favourable polishing properties. Based on the technology of the clinically proven composites Tetric EvoCeram and Tetric EvoCeram Bulk Fill, Tetric PowerFill utilises the inorganic fillers: barium aluminium silicate glass, an Isofiller, ytterbium fluoride and a spherical mixed oxide, amounting to an overall filler content of approximately 79%.

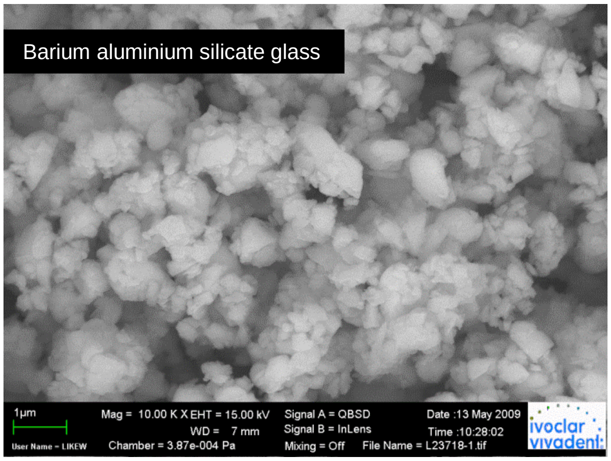


Fig. 8a: Barium aluminium silicate glass

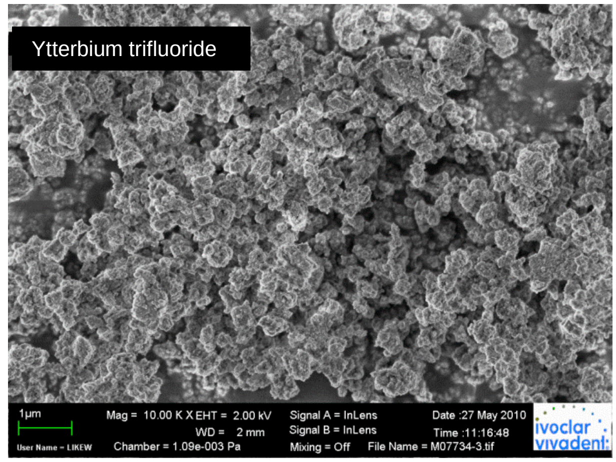


Fig. 8b: Ytterbium trifluoride

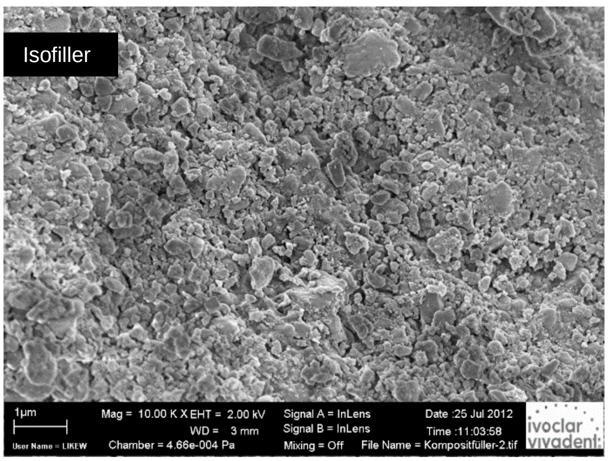


Fig. 8c: Isofiller: Shrinkage stress reliever

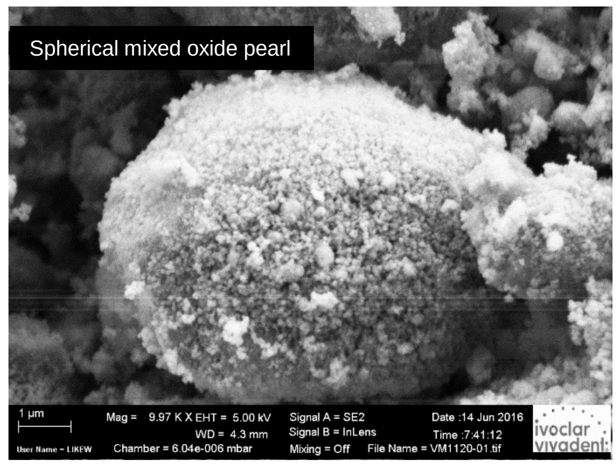


Fig. 8d: Spherical mixed oxide

The barium aluminium silicate glass with two different mean particle sizes imparts strength to the composite. The "Isofiller" is a copolymer composed of cured dimethacrylates, glass filler and ytterbium fluoride and is instrumental in lowering shrinkage and shrinkage stress (see below). Ytterbium fluoride confers high radiopacity and is capable of releasing fluoride. Spherical mixed oxide provides the basis for reduced wear and favourable consistency. The spherical particles minimize 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 esthetic 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.

Shrinkage stress reliever

Composite resins shrink during polymerization – this being the original rationale behind applying and polymerizing composites in 2 mm increments. Tetric PowerFill is a bulk fill composite designed for application in increments of up to 4mm, thus reducing polymerization shrinkage to a minimum is paramount. Problems associated with polymerization shrinkage include marginal discoloration, marginal gaps, secondary caries, cracking and hypersensitivity. Tetric PowerFill utilizes the same patented Isofiller (partially functionalized by silanes), as Tetric EvoCeram Bulk Fill. The following diagram illustrates its mechanism:

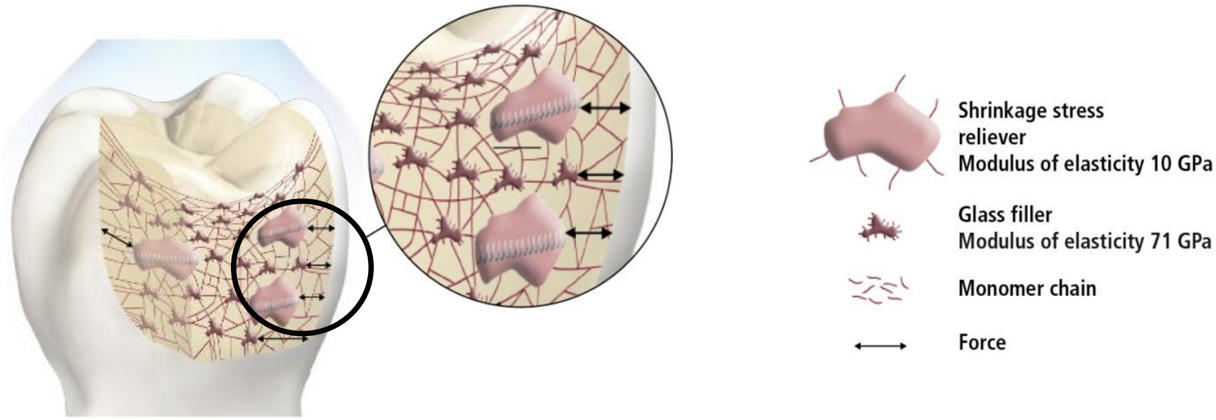


Fig. 9: Schematic representation of the shrinkage stress reliever (Isofiller) in a Tetric Power Fill restoration acting like a spring and reducing stress within the restoration

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 PowerFill acts like a spring (expanding slightly as the forces between the fillers grow during polymerization) amongst the standard glass fillers which have a higher elastic modulus of 71 GPa. As a result, these Isofillers are capable of accommodating the tensile stresses that occur during polymerization.[18] 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 PowerFill are reduced during polymerization – allowing increments of up to 4mm to be placed whilst ensuring a tight marginal seal.

Polymerization technology

Light-curing composites “set” by way of free radical polymerization. Incoming photons from the curing light are absorbed by photoinitiator molecules. The energy absorbed excites the molecules, and in their active state, radicals are formed (if one or several activators are present) and this triggers polymerization. Initiator molecules can however only absorb the photons of a specific spectral range. As customary resin materials are polymerized with visible blue light, the light-absorbing initiators used have an inherent yellow colour as this is the complementary colour to blue light. On curing, this yellow colour largely disappears. 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 polymerize 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. Tetric PowerFill therefore utilizes the photoinitiators camphorquinone and Ivocerin.

Camphorquinone used together with a tertiary aromatic amine (as a coinitiator for accelerated polymerization) is widely used in polymer synthesis. Camphorquinone has a light absorption spectrum of approximately 410 nm to 500 nm, with a peak maximum of 470 nm within the blue wavelength range.

Ivocerin is a recently developed photoinitiator from Ivoclar Vivadent. This dibenzoyl germanium derivative was first introduced with the bulk fill composites Tetric EvoCeram Bulk Fill and Tetric EvoFlow Bulk Fill, which can both be applied and cured in up to 4 mm increments. It features a light absorption spectrum of approximately 370nm to 460nm with a peak sensitivity at around 410 nm within the violet wavelength range. Ivocerin absorbs light at a higher wavelength range than acyl phosphine oxide (see section 1.3, Generations of LED light), and can therefore be activated by all commercially available halogen and LED lights.

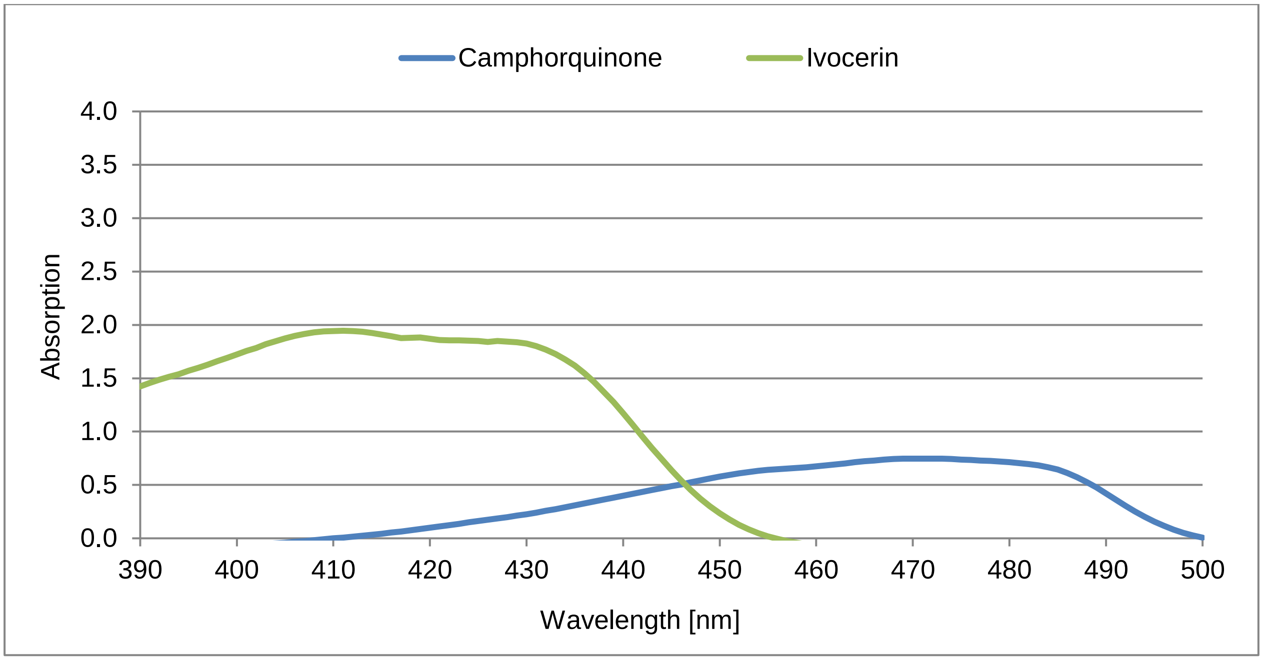


Fig. 10: Absorption spectra of camphorquinone and Ivocerin (R&D Ivoclar Vivadent 2012)

Tetric PowerFill can therefore be cured with blue light within the wavelength range of approximately 400 to 500nm. The inclusion of Aessencio technology (see section 2.3) whereby the translucency of the composite reduces from approximately 25% to 17% during polymerization, also enhances depth of cure by allowing greater light penetration at the outset. The Aessencio technology effect is more pronounced in the flowable composite Tetric PowerFlow.

Ivocerin and depth of cure

Ivocerin features a high absorption coefficient allowing for increased quantum efficiency. This means it is far more light-reactive than e.g. campohorquinone, enabling the material to polymerize more rapidly and with greater depth of cure. The use of Ivocerin as a "polymerization booster" also allows the translucency to be set at an enamel-like translucency of approximately 17%. Light penetration is sufficient, such that Tetric PowerFill can be cured in 4mm increments and in contrast to Tetric EvoCeram Bulk Fill this is possible in just 3 seconds.

Fig. 11: Schematic representation of 4mm curing in Tetric PowerFill with Ivocerin

Other than demonstrating a more rapid polymerization process due to enhanced reactivity, composites containing Ivocerin exhibit excellent bleaching behaviour (from their initial yellow colour) and require a considerably lower photoinitiator concentration to achieve comparable mechanical properties. This is useful as it means its polymerization-boosting properties can be used without negatively affecting the optical properties of tooth-coloured pastes with enamel-like translucency.

Light sensitivity filter

A composite that is applied in 4 mm increments and subsequently contoured, needs to provide sufficient working time before it begins to polymerize. As dental composites contain photoinitiators that react to blue light, both ambient light and dental operating lights (which contain blue light) are capable of triggering premature polymerization. Notably the inclusion of the highly reactive Ivocerin makes a light sensitivity filter imperative. Tetric PowerFill incorporates the same patented light sensitivity filter used in Tetric EvoCeram Bulk Fill, which provides a working time of more than three minutes - under defined light conditions of 8000 lux. Importantly whereas the stabilizer/inhibitor delays the polymerization process in the presence of “low level” blue light, it does not impair curing under the intensive blue light of a polymerization unit.

2.3 Tetric® PowerFlow

Tetric PowerFlow is a light-cured, flowable, radiopaque, bulk fill composite for the direct restorative treatment of posterior teeth. It is identical to Tetric EvoFlow Bulk Fill. Aimed at users who prefer a flowable material for large volume replacement, Tetric PowerFlow is applied as an initial layer in increments of up to 4mm in Class I and II restorations and covered with a surface layer of compatible sculptable composite. Like Tetric PowerFill, it is cured with light in the wavelength range of 400 to 500 nm.

As a stand-alone product, cured with a conventional curing lamp with a light intensity/irradiance of up to 2000mW/cm^2, it can be used as a first increment in Class I or II restorations in permanent posterior teeth or for the restoration of deciduous teeth. It can then be covered with a universal or posterior composite such as Tetric EvoCeram, Tetric EvoCeram Bulk Fill or the new Tetric PowerFill.

As part of the 3s PowerCure-System, Tetric PowerFlow (like Tetric PowerFill) is only indicated for restorations in the posterior region of permanent dentition (Class I and II) when light cured from the occlusal aspect. Very deep cavities and cases of caries profunda are contraindicated, as this curing mode is unsuitable for areas close to the pulp. For 3-second curing, the Bluephase PowerCure light is utilized in 3s PowerCure-Mode. Tetric PowerFlow is applied in bulk, cured for 3 seconds, and then covered with a layer of Tetric PowerFill which is also cured for 3 seconds. Tetric PowerFlow can also be applied as an initial liner e.g. prior to a bulk increment of Tetric PowerFill. Tetric PowerFlow is colour-matched to Tetric PowerFill and is available in the same three universal shades: IVA, IVB and IVW.

Composition

Tetric PowerFlow is identical to Tetric EvoFlow Bulk Fill and is chemically similar to its counterpart Tetric PowerFill, containing similar fillers and monomers. As a flowable material the monomer matrix comprises a higher percentage (approx. 34%) of the composite than the sculptable (more viscous) Tetric PowerFill (approx. 18%). The filler content is correspondingly somewhat lower, accounting for approximately 71% (as opposed to 79%) of the material. Tetric PowerFlow utilizes the same camphorquinone/amine and Ivocerin initiator system as Tetric PowerFill, the same shrinkage stress reliever and light sensitivity filter (see relevant sections in chapter 2.2 relating to Tetric PowerFill). Due to its higher monomer content and resulting lower surface hardness compared with sculptable composites Tetric PowerFlow is always finished with a covering of a high viscosity/sculptable composite.

Aessencio Technology

Tetric PowerFlow incorporates Aessencio Technology. This refers to the increase in opacity (decrease in translucency) that the composite undergoes during polymerization. In its uncured state, the translucency of Tetric PowerFlow is approximately 28%. This allows blue light to penetrate the composite and initiate polymerization at depth. After polymerization, Tetric PowerFlow exhibits a natural low dentin-like translucency of less than 10% [18], allowing for the masking of discoloured tooth structure.

The following diagram illustrates the effect with samples of Tetric PowerFlow, pre and post polymerization over a striped background.

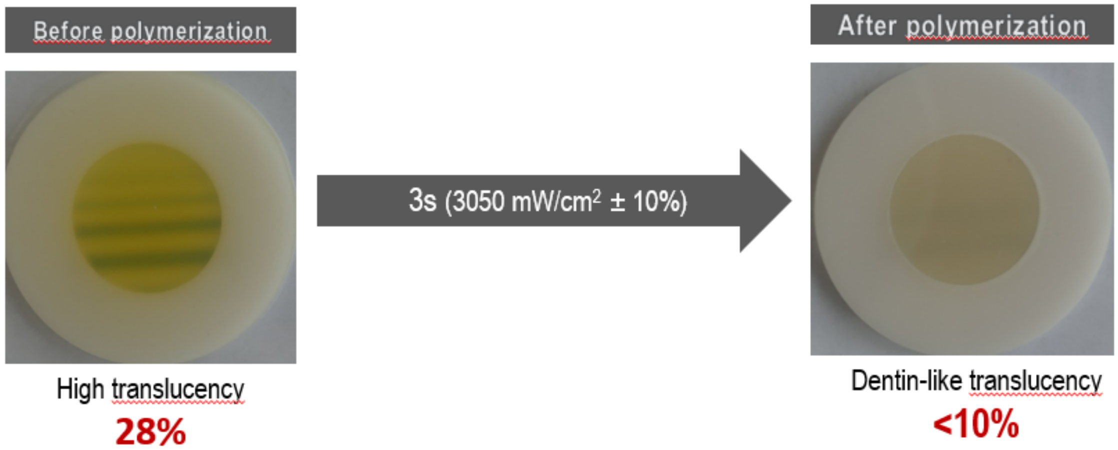


Fig. 12: Demonstration of Aessencio technology in Tetric PowerFlow over a striped background

The combination of Aessencio Technology and the polymerization booster Ivocerin allows the apparent contradiction of high curing depth and simultaneous dentin-like translucency to be overcome. The change in translucency is caused by the change in the refractive index that occurs when uncured monomer is converted into a polymer matrix.[18] The refractive index is defined as follows:

$$\text{Refraction} = n = \frac{c_O}{c_M} = \frac{\text{Speed of light in vacuum}}{\text{Speed of light in the medium}}$$

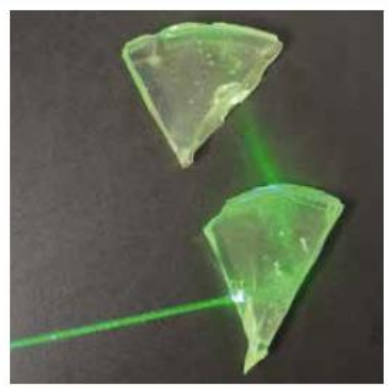


Fig. 13: Equation for calculating the refractive index and illustration of laser beam refraction on entering and leaving a material

The refractive index characterizes an optical (non-dimensional) property of a material. It determines how much a path of light is bent, or refracted, when entering a material. Each substance has its own characteristic refractive index. The refractive index can be determined for each constituent material of a composite. For the sake of simplicity, a single refractive index value is assigned to the monomer mixture based on its constituents. Each individual filler also has its own characteristic refractive index. During polymerization whereby the initiators form radicals and the radicals react with the monomers to create a polymer network- the refractive index increases. Light is refracted differently through a polymerized composite than through an unpolymerized mixture – altering the optical properties. As such, the refractive index of the matrix has changed but the indices of the individual fillers remains unaltered. [18]

This process of refractive index change following polymerization can be ideally harnessed for materials whereby the goal is to achieve good depth of cure in large increments. For this purpose, the refractive index of the unpolymerized monomer mixture is matched to the refractive indices of the fillers. This results in a highly translucent paste. When the composite polymerizes, the light can travel through the translucent filling without impediment. Due to the highly reactive initiator Ivocerin, the material polymerizes rapidly and reliably, even in deep areas at the interface to the tooth structure. With progressive polymerization, translucency decreases and the composite becomes more opaque. This reduced translucency lends Tetric PowerFlow a dentin-like opacity and the ability to mask discoloration.

Both Tetric PowerFill and Tetric PowerFlow are the result of a coordinated optimized mixture of monomer matrix and fillers. Tetric PowerFlow is the perfect complement to Tetric PowerFill with both products coordinated in terms of dentin like and enamel like translucency (respectively), shading and handling.

2.4 Bluephase® PowerCure

The Bluephase PowerCure is a stylish 4th generation (4G), high-power, polywave, cable-free LED curing light, offering dental professionals the absolute state of the art in dental curing. The unit offers four curing programs or varying light intensity, with various associated curing times for different indications:

The **PRE** (PreCure program) emits a light intensity of 950 mW/cm^2 ± 10% and is used to tack-cure adhesive luting composites such as Variolink Esthetic, in order to facilitate the easy removal of excess material. The program is pre-set to last two seconds only.

The **H** (High Power program) emits a light intensity of 1200 mW/cm^2 ± 10% with selectable curing times of 5, 10 or 20 seconds - as appropriate.

The **T** (Turbo program) emits a higher light intensity of 2100 mW/cm^2 ± 10% with a fixed curing time of 5 seconds.

The **3s** (3s PowerCure program) emits the highest light intensity at 3050 mW/cm^2 ± 10% with a fixed curing time of 3 seconds.

Fig. 14: Bluephase PowerCure curing light

The Bluephase PowerCure unit with its four different light-irradiance programs, is suitable for use with all light-curing dental materials that can be polymerized in the wavelength range of 385-515nm – assuming manufacturer instructions for use are adhered to.

2.4.1 3s PowerCure Program

The Bluephase PowerCure is a universal unit suitable for curing both composites and adhesives (applied near to the pulp), however the state of the art 3s PowerCure-Mode with a light intensity of 3050 mW/cm^2 is only suitable for the occlusal curing of Class I or II direct restorations in the posterior region, when an ideal positioning of the lamp over the composite can be assured. The 3s PowerCure program is not suitable for deep cavities/cases of caries profunda.

The 3s PowerCure program is for use in combination with Adhese Universal, Tetric PowerFlow and Tetric PowerFill. Each layer of product is cured in 3 seconds. As is the case with all high-performance curing lights, the high level or irradiance results in a certain amount of heat development. The 3s PowerCure program can therefore only be activated twice in direct succession. After two curing cycles, a 30-second break is necessary before the next curing cycle can be activated. This is a safety precaution to avoid any potential damage to the pulp or mucous membranes from over exposure on the same tooth. The restriction to occlusal curing of Class I or II restorations also provides for gingival protection and if soft tissue exposure cannot be avoided a lower intensity program is recommended.

2.4.2 Polywave technology

As previously noted, Bluephase PowerCure features polywave technology, referring to the use of both blue and violet light-emitting LEDs – resulting in a wavelength spectrum of between 385 and 515nm with two spectral peaks at approximately 410nm and 460nm.

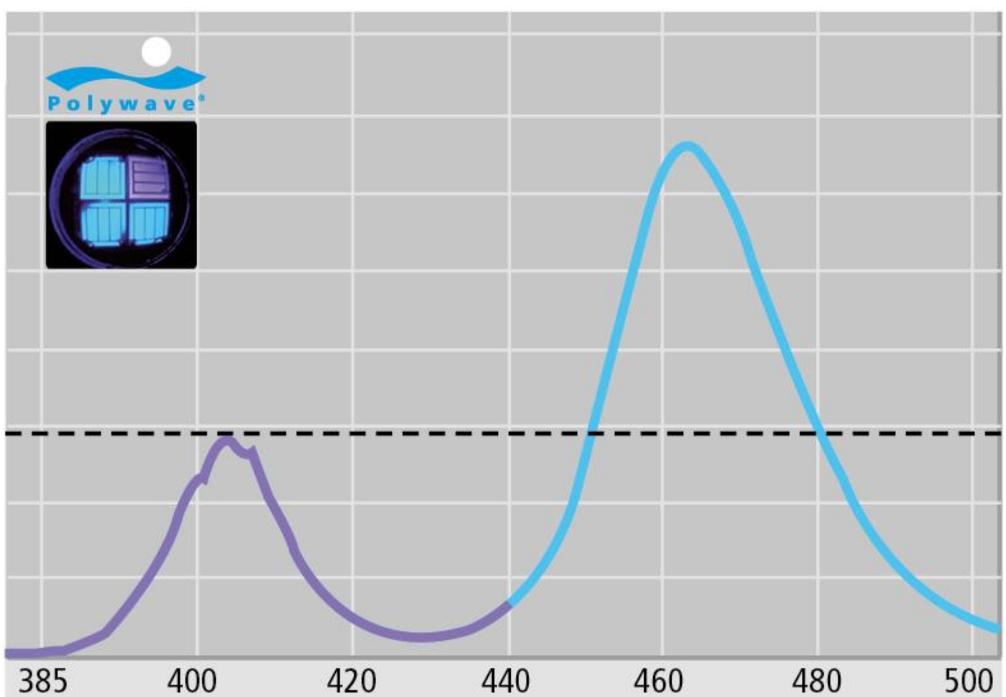


Fig. 15: Blue and violet LEDs and their respective wavelength spectra illustrating dual peak/polywave technology

In contrast to the Bluephase Style (polywave) curing light which utilizes two blue light LEDs and one violet LED, the Bluephase G4 and Bluephase PowerCure lights employ three blue light LEDs and one violet. The light spectrum as measured via spectrometer, illustrating the double-peak is shown below.

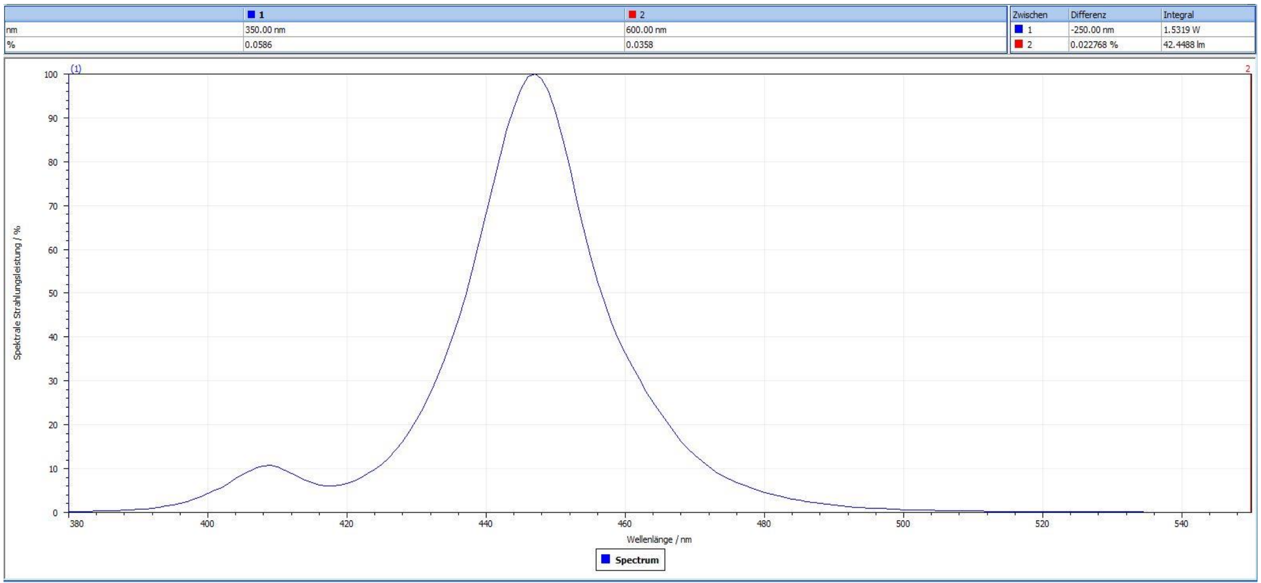


Fig 16: Dual peak spectrum of 3s PowerCure program of Bluephase PowerCure, as measured by Spectrometer CAS 140 CT

Light intensity/irradiance and dose

Light intensity/irradiance is best measured using an integrating sphere. The light emitted from the light guide is measured, determining the exact emissive power in mW. Appropriate filters ensure that only light in the effective wavelength range is measured and the light intensity in mW/cm^2 is calculated on the basis of the surface area of the light guide tip.

$$\frac{\text{Power [mW]}}{\text{Surface Area [cm}^2\text{]}} = \text{Irradiance [mW/cm}^2\text{]}$$

Fig. 17: Irradiance calculation

The “Total Energy” concept states that the process of light-induced polymerization is energy-dependent and basically a product of light intensity and time. Therefore, a curing time of 10 seconds at a light intensity/irradiance of 1200 mW/cm^2 results in a dose of 12,000 mWs/cm^2.

$$\frac{\text{Dose}}{\text{Irradiance}} = \text{Curing Time}$$

Fig. 18: Total Energy calculation

Logically the higher the intensity of the curing light, the shorter the necessary curing time. The following Bluephase curing lights have been shown to cure sufficiently when used with the appropriate composite material, for the following curing times:

	Bluephase Style HIGH mode	Bluephase Style 20i TURBO mode	Bluephase PowerCure 3s PowerCure-Mode
Dose (mWs/cm^2)	12000	10000	9150
Irradiance (mW/cm^2)	1200	2000	3050
Curing time (s)	10	5	3

Table 4: Dose calculations according to the "Total Energy" concept when using lights of varying intensity

A dose of approximately 9000 mWs/cm^2 was found to be sufficient for curing up to 4mm increments of Tetric PowerFill and Tetric PowerFlow.

2.4.3 Light guide

The light guide has a big influence on the efficiency of polymerization lights. If a curing light is designed without a light guide but equipped with an LED mounted at the front of the light-emission window, much of the irradiance is lost due to scattering at a certain distance from the object to be cured. Light guides comprised of fibre glass rods for light transmission, have proven invaluable in reducing this loss due to scattering. Light guides are either parallel or tapered - whereby the emission window is smaller than the shaft of the light guide. The Bluephase PowerCure light guide is very slightly tapered, decreasing in diameter from 10mm to 9mm. The Bluephase Style 20i light guide is slightly more tapered, decreasing from 10mm to 8mm. In contrast the Bluephase Style is equipped with a 10mm parallel light guide.

Tapering allows the light to be concentrated over a smaller surface area, achieving a high power density, i.e. higher light intensity/irradiance per surface area. This saves energy and facilitates the high irradiance capacity and lower curing times. If the tapering is extreme however e.g. from 13mm to 8mm it can have an adverse effect on the light-scattering characteristics. The scattering angle becomes wider and the light intensity decreases more rapidly as the distance from the composite to be cured increases. This is a particular problem in curing units where the LED is mounted right at the front of the light-emission window. The minimally tapered 10>9mm light guide of the Bluephase PowerCure optimizes irradiance whilst minimizing scattering. The pictures below, further illustrate the light scattering characteristics of curing lights with different shaped light guides or LED positions.

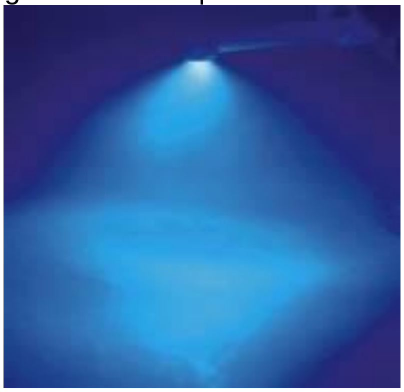


Fig. 19a: Diffuse light scattering when LED is mounted at front

Fig. 19b: Light scattering of a very tapered light guide (13>8 mm)

Fig. 19c: Homogeneous light scattering of a parallel light guide

Light guides and curing distance

Large curing distances cannot always be prevented in daily working routines however, for example when curing in deep cavities, or when curing luting composites through a ceramic restoration. Price et al,[19] reported that light intensity/irradiance is reduced to 50% of its full intensity at a distance of 6mm for a parallel light guide but to a very low 23% of its full intensity for a tapered light guide, at that distance.

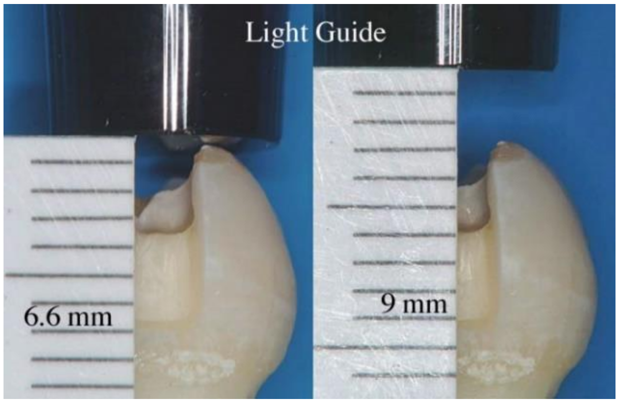


Fig. 20: Illustration of distances between the light guide and the composite material to be cured.

R. Price, Dalhousie University, Halifax, Canada

The graph below shows the loss of power for Bluephase PowerCure (10>9mm) compared to Bluephase Style 20i (10>8mm) and Bluephase Style (10mm parallel) from the initial maximum light output for each lamp, set at 100%. The loss is depicted with increasing distance (up to 10mm) from the material, as measured with an integrating sphere.

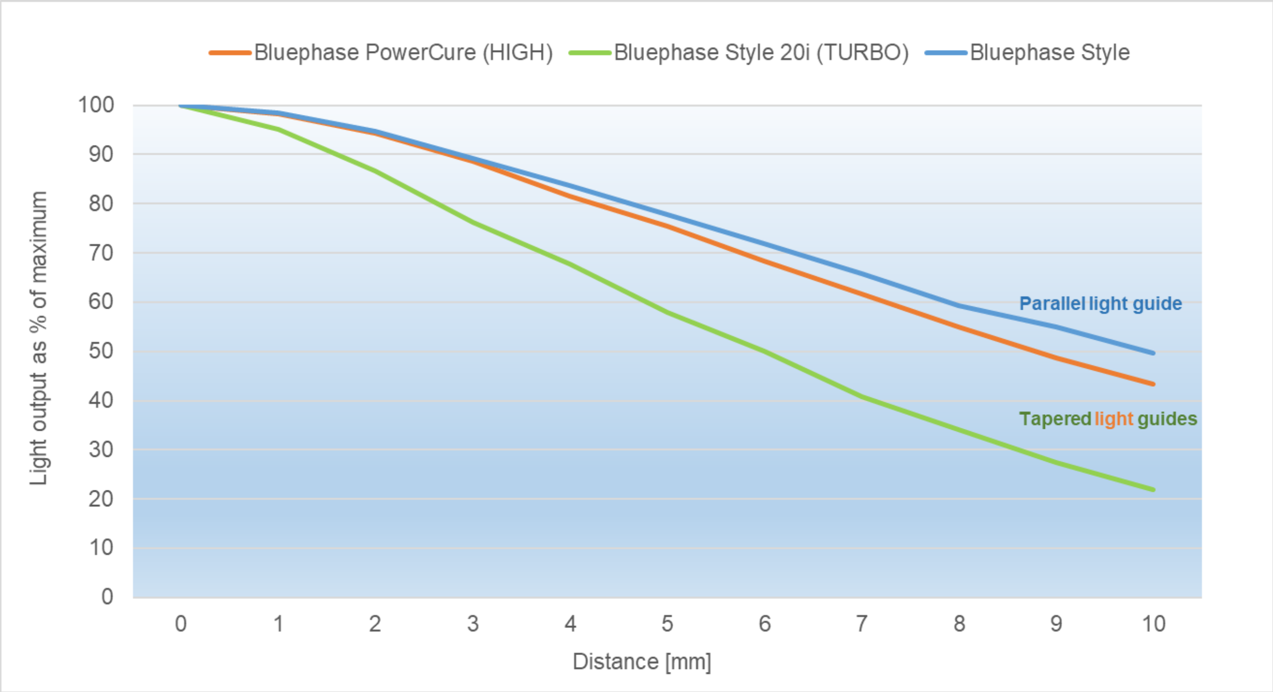


Fig 21: Fig. 7: Normalized light power of various Bluephase curing units with parallel and tapered light guides: Decrease in power as percentage of maximum at various distances. *R&D Ivoclar Vivadent AG, Schaan, 2016, 2018*

Bluephase Style with its 10mm parallel light guide, features the least reduced light output. Bluephase PowerCure with its very slightly tapered light guide features just slightly more loss – with this loss only becoming apparent after a distance of approximately 5mm.

The following diagram illustrates the light power loss at increasing distance for Bluephase PowerCure (see orange line), compared to various competitor lights.

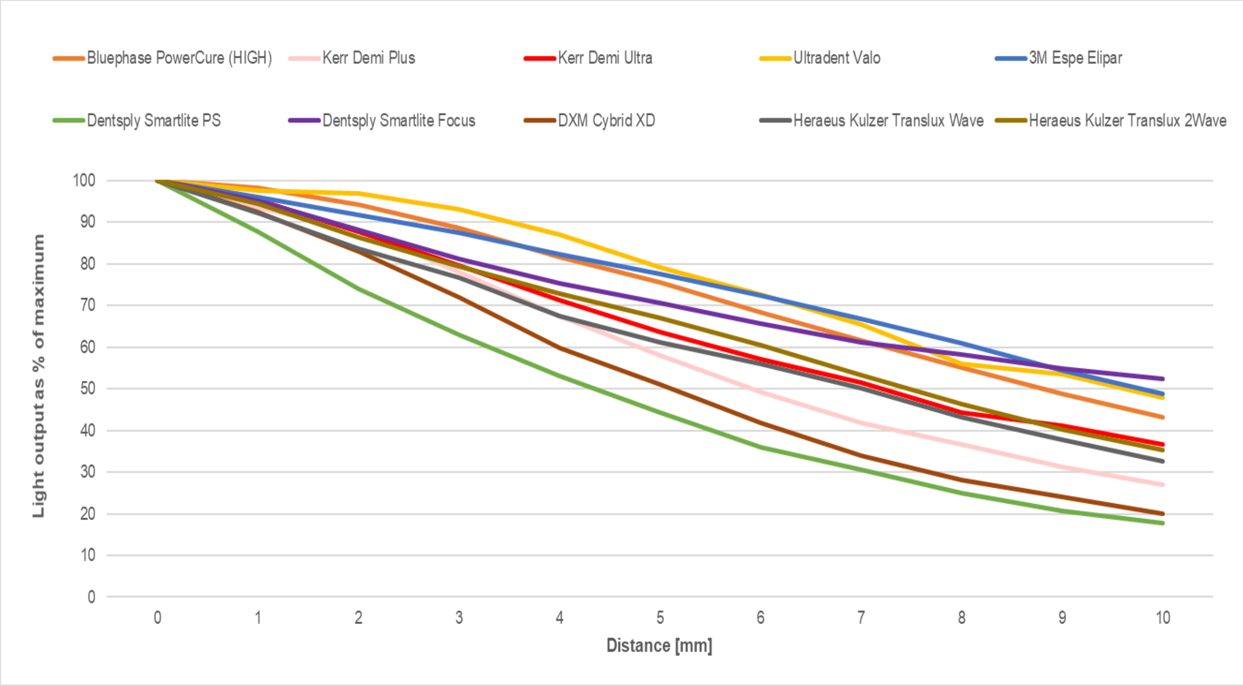


Fig. 22: Normalized light power of various LED lights. Decrease in power as percentage of maximum with increasing distance from material. *R&D Ivoclar Vivadent AG, Schaan, June 2018*

Bluephase PowerCure exhibits lower light loss over distance than many other lights. At a distance of 10mm the light output was 43% of that at 0mm distance. The light output is reduced to 50% of its initial value at a distance of over 8mm. Curing lights with more tapered light guides, such as DXM Cybrid XD (10mm - 8mm) and Kerr Demi Plus (13mm – 8mm) exhibit slightly higher loss of light power. Dentsply Smartlite PS features an LED built in at the light tip and this exhibited the greatest loss of power at distance.

2.4.4 Light homogeneity

The successful curing of composite materials is a two-way interdependent process between the restorative material and the curing light. For the curing light, the wavelength emission, light intensity/irradiance, curing time and light homogeneity are key; for the composite, critical factors include the initiators used, shade, optical translucency and any resulting shrinkage.

Bluephase PowerCure demonstrates excellent light homogeneity – this means the light emitted via the light guide is largely even and non-differential. Clinically this means the resin material being cured receives irradiance uniformly from the surface area of the light guide tip and not in an irregular pattern. This is crucial for achieving even depth of cure with a short curing time.

The diagram below illustrates the light-homogeneity of the Bluephase PowerCure as measured with a near field camera and cosinus filter, when illuminating from below. The diagram on the left illustrates a non-homogenous light emission situation whereby the ratio of the highest and lowest light emission is varied, giving a ratio of 1:2.7 and an optical picture similar to a sunken volcano. A perfectly homogenous ratio would be 1:1 with all light emission level. The diagram on the right shows the homogenous light emitted from the Bluephase PowerCure (G4) unit, exhibiting a very uniform ratio of 1:1.3, which optically gives a flatter (not sunken) image.

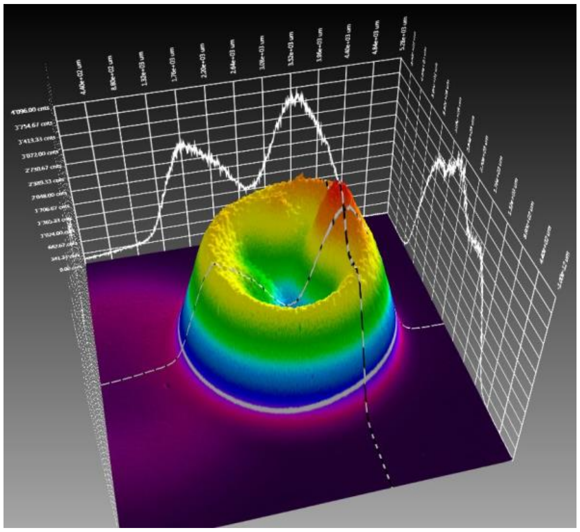


Fig. 23a: Non-homogenous light distribution (1:2.7)

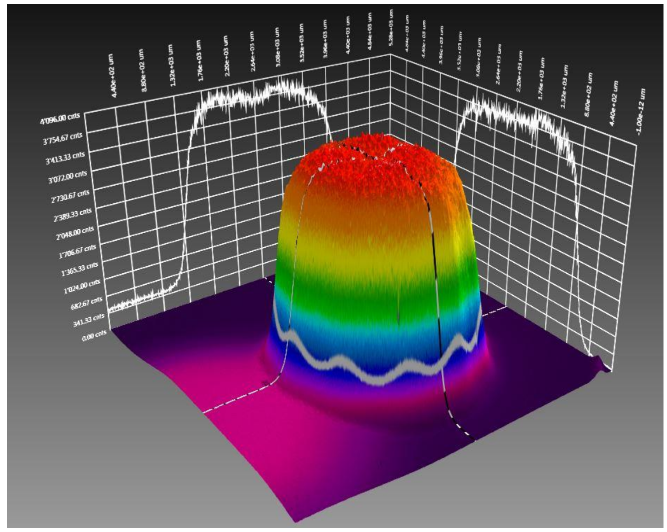


Fig. 23b: Homogenous light distribution of Bluephase PowerCure (1:1.3)

2.4.5 Polyvision

Polyvision®

The Polyvision effect operates via reflection. When the polymerization light is switched on with the Polyvision Automatic Assistant activated, blue light exits via the light guide. At the outset, only a low level of light output is emitted. If this low level of light meets a reflective surface (such as a tooth) it is then reflected back towards the light guide. The reflected light is measured and evaluated and if the reflection is rated sufficient, the selected polymerization program commences. If there is no object and therefore reflection (such as when the light is held up in the room and turned on accidentally) the lamp registers this lack of reflected light and turns itself off automatically. This is a rapid process occurring within 100ms.

After one second's use over the tooth, a reference value for the reflection is recorded. If the device is moved, the amount of light reflected changes (as teeth are uneven). If the movement and therefore change in reflection exceeds a given threshold, an "alarm" is triggered in that the Polyvision icon flashes and acoustic signals are emitted. The curing time is then automatically extended by 10% to compensate for the "slippage". If the device moves excessively e.g. completely away from the tooth/material being cured, the loss of reflection is recorded and the light switches off. The Polyvision reflection mechanism therefore offers the user two built-in checking systems: Anti-glare protection for the eyes from inadvertent or accidental use outside the patient's mouth and safe-polymerization protection (inside the patient's mouth) – should inadvertent hand slippage occur.

The Polyvision function can be switched off by pressing on the time or program selection button for > 2 seconds, whereby the Polyvision symbol at the bottom of the handpiece disappears.

2.4.6 Bluephase PowerCure Base

Adequate polymerization is a decisive factor when it comes to the clinical success of a composite restoration. Incompletely cured restoratives may cause postoperative sensitivity and even necessitate endodontic treatment. Although the light output is always stipulated by light manufacturers, studies have indicated that curing lights often operate at sub-optimal levels. An Australian survey of 214 lights in use in dental practices found that over 50% were not functioning satisfactorily. Lower light intensities than those stated by manufacturers were evident, particularly in older light curing units.[20]

The Bluephase PowerCure handpiece holder (base) offers dentists the convenience of checking the light output/irradiance level of the unit at regular intervals. The base doubles-up as a basic radiometer, allowing the optimal curing function of the light to be reviewed as desired.

Fig. 24: Bluephase PowerCure and base with integrated light output measuring function

The Bluephase PowerCure radiometer-base is only suitable for testing the Bluephase PowerCure light itself. For other commercially available lights, including other Bluephase units, the Bluephase Meter II is recommended.

3. Technical Data

3.1 Adhese Universal

Function	Substance/Component	Weight %
Monomer	**Methacrylates and dimethacrylates**	60 - 70
Crosslinker		
Adhesive additive		
Solvent	**Ethanol and water**	23 - 28
Film-former	**Silicon dioxide**	3 - 5
Initiators and Stabilisers	**Initiators and stabilisers**	3 - 5

Characteristics	Unit	Specification
Shear bond strength (Dentin)	MPa	≥ 25*
Shear bond strength (Enamel) **(in combination with direct filling composites, light-curing composite cements, light-curing core build-up composites)**	MPa	≥ 17*
Shear bond strength (Enamel) **(in combination with self-curing core-build up materials)**	MPa	≥ 14*

* 4 from 5 test pieces

3.2 Tetric PowerFill / Tetric PowerFlow

		Weight %	
Function	**Substance/Component**	**Tetric Power Fill**	**Tetric PowerFlow**
Filler	**Ba-Al-Silicate glass, Copolymer, Ytterbium trifluoride**	79	71
Monomer	**Dimethacrylates**	18	28
Viscosity modifier	**Additive**	3	1
Initiator and Stabilisers	**Initiators and stabilisers**		
Pigments	**Pigments**		

			Specification	
Characteristics[1]	***Note(s)***	**Unit**	**Tetric PowerFill**	**Tetric PowerFlow**
Sensitivity to ambient light		s	> 120	≥ 180
Depth of Cure	[2]	mm	≥ 4.0	≥ 4.0
Flexural strength		MPa	≥ 80	≥ 80
Transparency (after 24 h)		%		≤ 10
Water sorption (7 days)		µg/mm³	≤ 40	≤ 40
Solubility (7 days)		µg/mm³	≤ 7.5	≤ 7.5
Radiopacity	[3]	%	≥ 250	≥ 200
Wave length for polymerization		nm	400-500	400-500

These products meet the relevant performance criteria as defined in
EN ISO 4049:2009 - Dentistry – Polymer-based restorative materials (ISO 4049:2009)

[1] Physical and mechanical properties

[2] The method for determining the curing depth for the specific acceptance criteria of Ivoclar Vivadent, was a Vickers Hardness measurement which is supported by ISO 10477:2004

[3] Relative equivalence to ≥ 1mm Al

3.3 Bluephase PowerCure

<table>
<tr><td>Light source</td><td colspan="3">Ivoclar Vivadent Polywave LED</td></tr>
<tr><td>Wavelength range</td><td colspan="3">385 - 515 nm</td></tr>
<tr><td>Light intensity</td><td colspan="3">3s PowerCure program: 3050 mW/cm^2 ± 10 %
Turbo Program: 2100 mW/cm^2 ± 10 %
High Power Program:1200 mW/cm^2 ± 10 %
PreCure Program: 950 mW/cm^2 ± 10 %</td></tr>
<tr><td>3s PowerCure-Mode:
Curing times</td><td>Adhese Universal
3s</td><td>Tetric Power Fill
3s</td><td>Tetric Power Flow
3s</td></tr>
<tr><td>Operation</td><td colspan="3">3 min on / 7 min off (intermittent)</td></tr>
<tr><td>Light guide</td><td colspan="3">Tapered: 10 > 9 mm autoclavable</td></tr>
<tr><td>Signal transmitter</td><td colspan="3">Beeps every 10 seconds and every time Start/Stop button or Time/Program button is activated, anti-glare protection is enabled or curing process is aborted. 30-second waiting time after the 3s PowerCure program has been used twice in succession.</td></tr>
<tr><td>Dimensions of handpiece</td><td colspan="3">L= 170 mm, B = 30 mm, H = 30 mm</td></tr>
<tr><td>Weight of handpiece</td><td colspan="3">135 g (incl. battery and light guide)</td></tr>
<tr><td>Operating voltage of handpiece</td><td colspan="3">3.7 VDC with battery
5 VDC with power pack</td></tr>
<tr><td>Operating voltage of charging base</td><td colspan="3">5 VDC</td></tr>
<tr><td>Power supply</td><td colspan="3">Input: 100–240 VAC, 50–60 Hz max 1 A
Output: 5 VDC / 3 A
Manufacturer: EDAC POWER ELEC.
Type: EM1024B2</td></tr>
<tr><td>Operating conditions</td><td colspan="3">Temperature: +10 °C to +35 °C
Relative humidity: 30 % to 75 %
Ambient pressure: 700 hPa to 1060 hPa</td></tr>
<tr><td>Dimensions of charging base</td><td colspan="3">D = 110 mm, H = 55 mm</td></tr>
<tr><td>Weight of charging base with radiometer</td><td colspan="3">145 g</td></tr>
<tr><td>Charging time</td><td colspan="3">Approx. 2 hours (when battery empty)</td></tr>
<tr><td>Power supply of handpiece</td><td colspan="3">Li-ionen battery</td></tr>
<tr><td>Transportation and storage conditions</td><td colspan="3">Temperature: -20 °C to +60 °C
Relative humidity: 10 % to 75 %
Ambient pressure: 500 hPa to 1060 hPa
The curing light must be stored in closed, roofed rooms and not be exposed to severe jarring.
Battery:
- Recommended storage temperature: 15–30 °C / 59–86 °F, should not be stored at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period).
- Keep battery charged and store no longer than 6 months.</td></tr>
</table>

4. 3s PowerCure-System: Time saving

For dental personnel, the obvious advantages of the 3s PowerCure-System are related to time saving and a reduction in technique sensitivity coming directly from that time saving. When a composite is only cured for 3 seconds the perceived level of concentration necessary for e.g. keeping a steady hand over the restoration to be cured, is notably less than that necessary for a 10 second (or longer) period. The 3s PowerCure-System utilizing Adhese Universal, Tetric PowerFill, Tetric PowerFlow and the Bluephase PowerCure is the first system of this kind. As an open system - all the products can be used in a conventional manner also. The Ivoclar Vivadent International Center for Dental Education (ICDE) carried out a comparison of the potential time-saving with the system when compared to a traditional 2mm layering technique.

Comparison of traditional layering technique with Tetric EvoCeram and bulk layering technique with Tetric PowerFlow and Tetric PowerFill

Dr. A. Lebedenko. ICDE, Ivoclar Vivadent, Schaan, Liechtenstein (2018)

Objective

The goal of the investigation was to establish the time-saving effect of placing fillings via the traditional layering method compared to the 3s PowerCure bulk fill method.

Method

Five dentists carried out one of each type of filling in a 6mm OD cavity in tooth 16 of an esthetic preparation model.

Conventional restorations	Curing	3s PowerCure restorations	Curing
Adhese Universal	10s	Adhese Universal	3s
TetricEvoFlow: 1.5mm	10s	Tetric PowerFlow: 4mm	3s
Tetric EvoCeram: 2mm (4-6 increments)	10s	Tetric PowerFill: 2mm	3s

Table 5. Restoration materials and layers for time comparison

Adhese Universal was used for both restorations and applied according to the instructions for use. For the conventional restorations, an initial 1.5mm layer of Tetric EvoFlow was applied followed by Tetric EvoCeram using the traditional 2mm-technique using between 4 to 6 increments depending on the operator's preference. As a comparison, Tetric PowerFlow was applied in a 4mm increment and covered with a 2mm increment of Tetric PowerFill. For the conventional restorations, each step/layer was cured for 10 seconds with the Bluephase PowerCure in High Mode (H) at 1200mW/cm^2. The 3s PowerCure steps/layers were cured for 3 seconds using the Bluephase PowerCure in 3s PowerCure-Mode at 3050mW/cm^2. The time required for each step (and in total) with both types of restoration, was recorded and compared.

Results

As the same adhesive (Adhese Universal) was applied in the same way for both restorations, the adhesive step essentially only differed in terms of the polymerization time i.e. 3 seconds versus 10 seconds. This 7-second saving, when averaged across all the operators resulted in a 14% time saving for the 3s PowerCure restorations. The flowable materials (Tetric EvoFlow and Tetric PowerFlow) were also compared with one another and here the average 6-second time saving with the 3s PowerCure restorations is also largely attributable to the reduced polymerization time. Four out of five dentists saved time with this step though one required slightly more time. Overall there was an average of a 16% time saving. The sculptable comparison (Tetric EvoCeram and Tetric PowerFill) exhibited an extreme time-difference as several layers were compared with one layer. Clearly the more layers that were used for the conventional filling, the greater the comparative time-saving with the 3s PowerCure restorations. The average application/ polymerization time was 6:37 minutes for the conventional fillings compared to 2:12 minutes for the 3s PowerCure restorations, giving a mean time saving of 4 minutes 26 seconds (67%). The following diagrams illustrate the mean overall time saving experienced by the five dentists. The traditional application required an average of 8 minutes 7 seconds and the 3s PowerCure method, an average of 3 minutes 28 seconds.

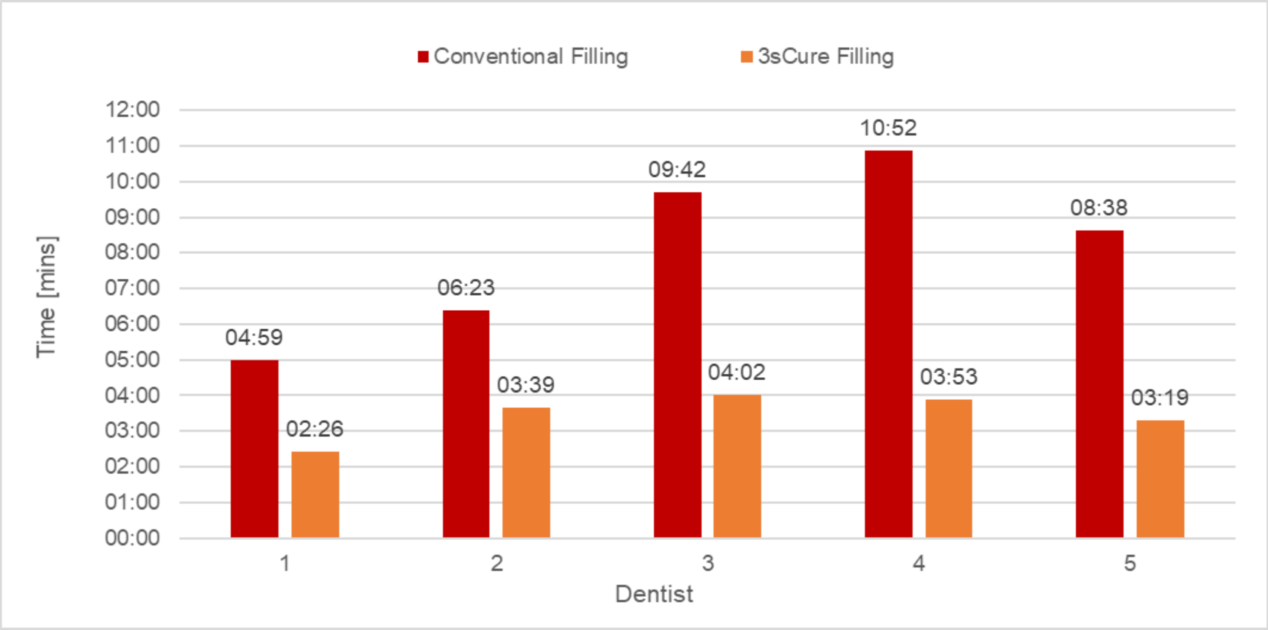


Fig.25: Application and polymerization times for conventional vs 3s PowerCure fillings for five dentists

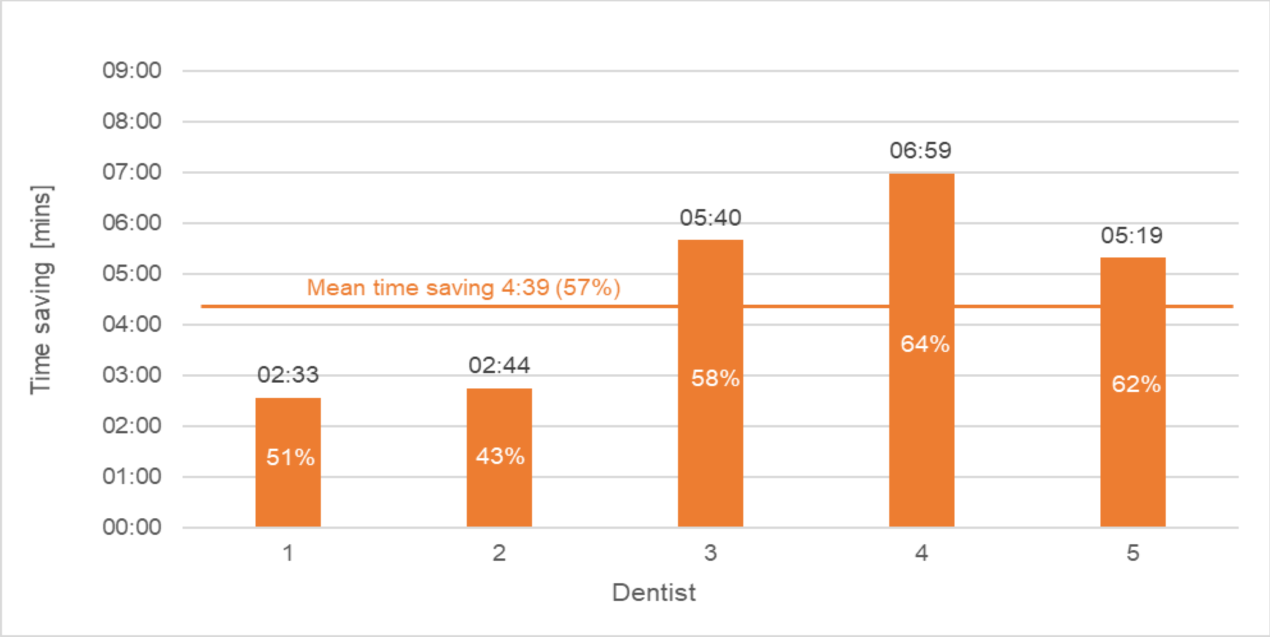


Fig.26: Time-savings with 3s PowerCure restorations compared to conventional fillings per dentist

Thus the average amount of time saved by performing the 3s PowerCure restoration as opposed to the conventional restoration was 4 minutes 39 seconds representing an average 57% time saving.

5. Materials Science investigations with the 3s PowerCure materials

Numerous *in vitro* investigations are carried out during the development phase of a dental product. Though not capable of predicting clinical success directly, they are useful indicators and e.g. allow comparisons with similar products of established clinical performance.

5.1 Investigations with Adhese Universal

The incomplete polymerization of adhesives leads to weakened shear bond strengths on enamel and dentin. The single component, light cured adhesive, Adhese Universal has proven itself clinically since 2014, for both direct and indirect bonding procedures with all etching protocols (see Scientific Documentation for Adhese Universal). In the development of dental adhesives, the adhesive (bond) strength and marginal quality (adaptation) are of primary importance. Tests are characteristically carried out on extracted human or bovine teeth and usually take place with the counterpart i.e. direct/indirect restorations intended to bond to the tooth structure.

As a part of the 3s PowerCure-System, Adhese Universal was investigated regarding its efficacy together with Tetric PowerFill or Tetric PowerFlow when cured for 3 seconds with the Bluephase PowerCure light. Other curing protocols were however also tested to cover a range of possible clinical situations e.g. adhesive (3s PowerCure) and composite (10s cure at 1100mW/cm^2 with Bluephase Style).

5.1.1 Bond strengths to dentin and enamel

Shear bond strength (SBS) testing was carried out according to ISO TR 29022:2018 using bovine teeth (n=5). Specimens were stored in water at 37°C for 24h or 3 months and thermocycling (5 - 55°C) was carried out with a dwell time of 30s. The internal Ivoclar Vivadent criteria require that the SBS be ≥ 17 MPa for enamel and ≥ 25 MPa for dentin.

2mm vs 4mm: In order to ensure that bond strengths can be assured with either incremental composite layers (2mm) or bulk fill placement (4mm), shear bond strength tests on enamel and dentin were carried out with composite cylinders of different lengths. These were cured for 3 seconds with the Bluephase PowerCure in 3s PowerCure-Mode.

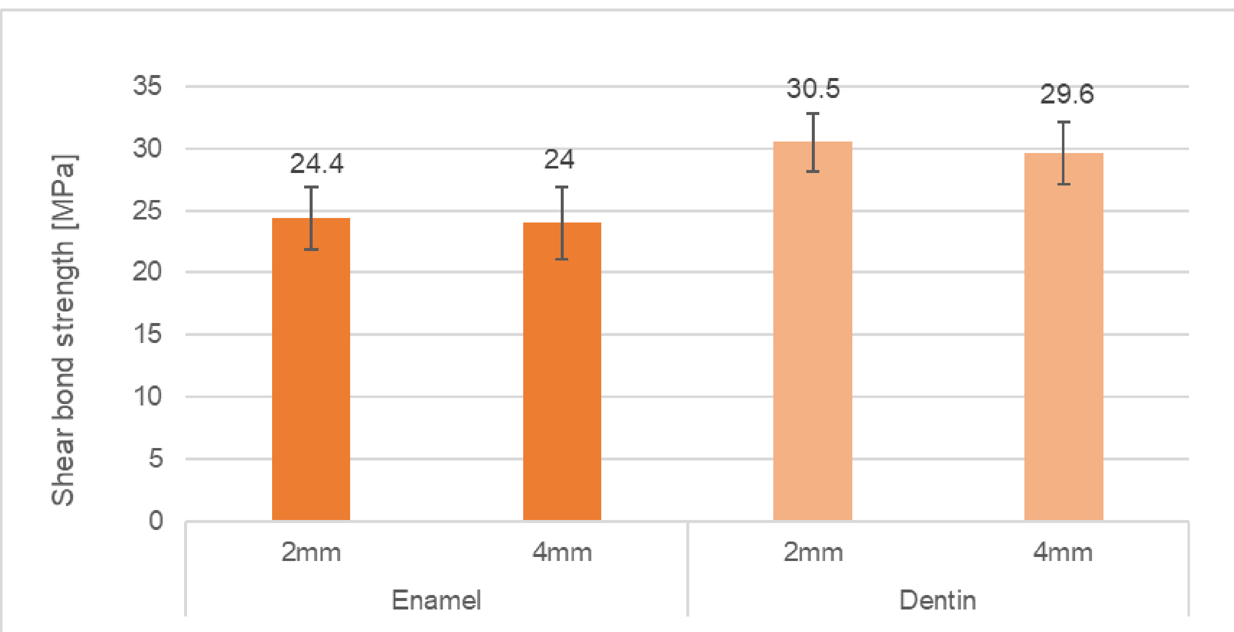


Fig. 27: 3s cured shear bond strengths after 24 hours on enamel and dentin with Adhese Universal (Self-Etch protocol) and Tetric PowerFill in 2mm and 4mm thicknesses

The increment thickness had no significant effect on the shear bond strength values for either dentin or enamel. The SBS values for the 4mm increments were very similar to the values for 2mm.

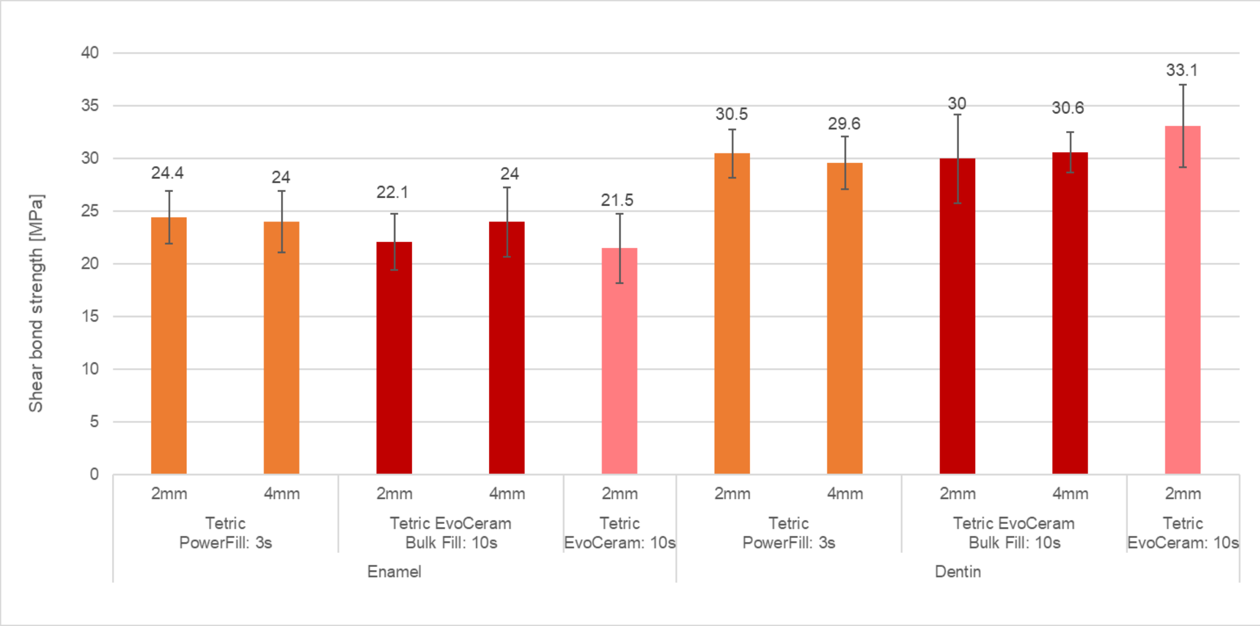


Fig. 28: Shear bond strengths after 24 hours on enamel and dentin with Adhese Universal (SE-Protocol) and Tetric PowerFill compared to Tetric EvoCeram Bulk Fill and Tetric EvoCeram in various thicknesses

As shown above, these values were also very similar to those achieved with Tetric EvoCeram Bulk Fill (in 2 and 4mm increments) and Tetric EvoCeram (only indicated for 2mm increments).

Durability: The long-term durability of the bond strengths on enamel and dentin after 3 second curing was also tested by storing 4mm specimens in water at 37°C for 24 hours, 3, 6, 12 and 24 months.

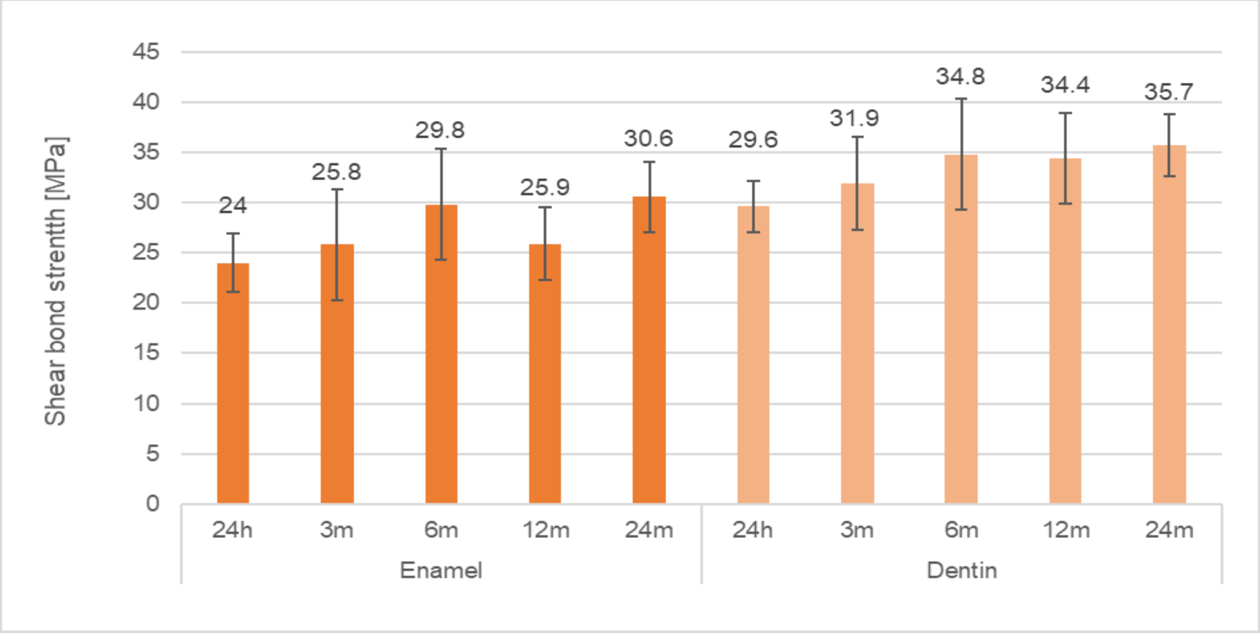


Fig. 29: 3s cured shear bond strengths over time on enamel and dentin with Adhese Universal (Self-Etch protocol) and 4mm increments of Tetric PowerFill

The bond achieved with Adhese Universal and Tetric PowerFill after 3 second curing remained stable over 24 months for both enamel and dentin remaining well over the threshold values of 17 and 25 MPa respectively over the time period.

Variable curing times: As an "open" system various curing times are possible with the 3s PowerCure materials. Adhese Universal + Tetric PowerFill or Adhese Universal + Tetric PowerFlow specimens therefore underwent shear bond strength testing after curing the adhesive or composite for various lengths of time.

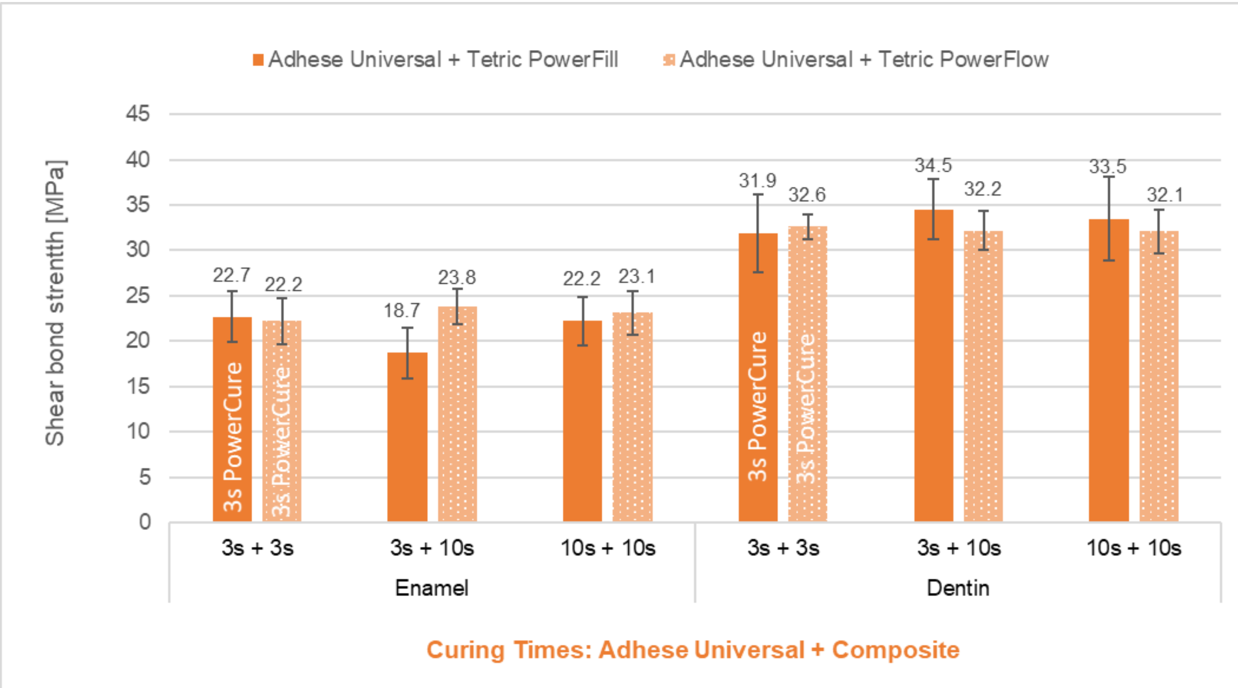


Fig. 30: Shear bond strengths after 24h water storage and various curing protocols on enamel and dentin with Adhese Universal (Self-Etch protocol) and 4mm increments of Tetric PowerFill or Tetric PowerFlow

The graph above illustrates the relatively constant values on enamel and dentin within each product group: Adhese Universal + Tetric PowerFill or Adhese Universal + Tetric PowerFlow, no matter which curing protocol was used. The shear bond strength values achieved using the 3s PowerCure method for both Adhese Universal and composite (3s + 3s), did not differ significantly from the other curing protocols.

DENTAL ADVISOR Product insights you can trust.

Self-Etch vs Total-Etch

Bond Strength Laboratory Evaluation of a new curing light and restoratives

Cowen M, Powers J.M. Dental Advisor, Ann Arbor, Michigan 48103 USA. (2019)

Objective: To establish the shear bond strengths achieved with the new 3s PowerCure-System in Self-Etch and Total-Etch mode compared to the same composites cured traditionally (10s) and Filtek One/3M Espe.

Method: Human adult third molars that had been extracted within the previous 3 months and sterilized in a 1% chloramine T solution, were embedded in acrylic resin discs and ground through 600-grit SiC paper to form bonding substrates of both superficial dentin and ground enamel. Specimens were then ultrasonically cleaned in deionized water for 5 minutes. 8 specimens per group were tested.

In the Total-Etch groups, Scotchbond Universal Etchant/3M Espe was used with the adhesive Scotchbond Universal and the composite Filtek One whereas the etchant Total Etch/Ivoclar Vivadent was used with Adhese Universal and Tetric PowerFill/Tetric PowerFlow.

The composites were placed on top of the bonding agents, utilizing the Ultradent Shear Test mould and jig to produce a 2.38 mm diameter test cylinder according to ISO 29022:2013. The composite cylinder and adhesive were either light cured for 3s in the 3s PowerCure mode with Bluephase PowerCure or for 10 seconds with Bluephase Style. The specimens were then transferred to a 37°C deionized water bath for 24 hours. Testing was then performed using an Instron 5866 at a crosshead speed of 1mm/min.

Results: The mean shear bond strengths established are shown in the graph below.

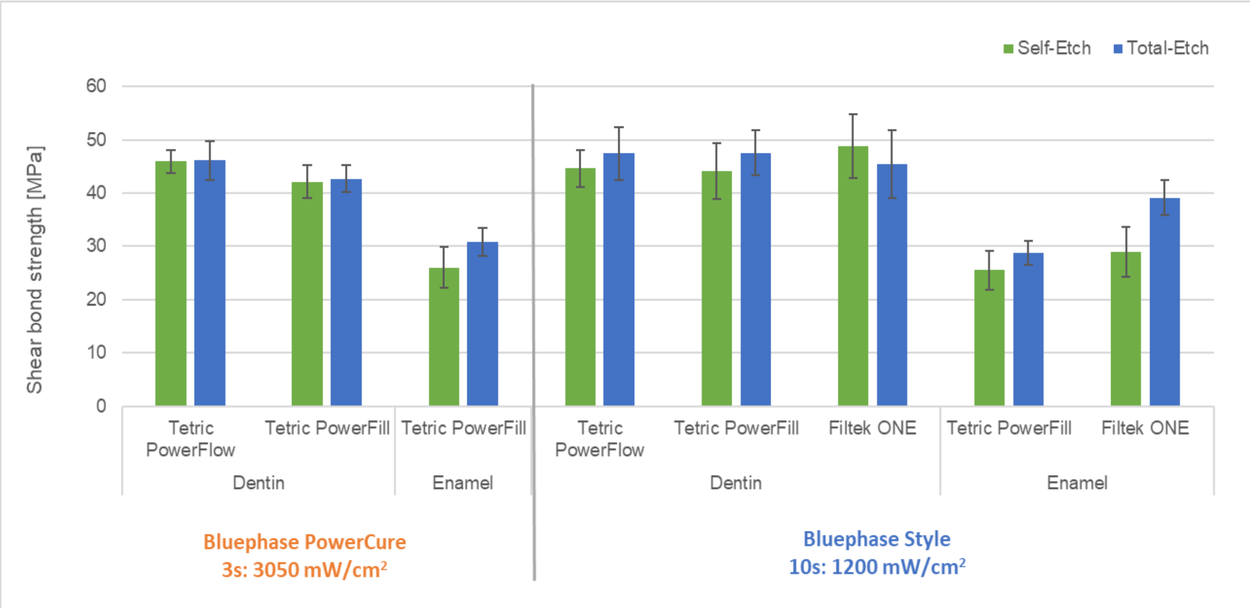


Fig. 31: Mean shear bond strengths on enamel and dentin for 3s PowerCure composites and Filtek ONE under various curing protocols

Conclusion:

The shear bond strengths were largely very similar whether the Total-Etch or Self-Etch protocol was used for each product or which curing protocol was implemented.

5.1.2 Composite Repair

As composite-based materials are also repaired with other resin-based materials, various combinations of products were tested regarding shear bond strength after repair. Tetric PowerFill, Tetric EvoCeram Bulk Fill and Tetric EvoCeram were all tested as potential substrates which were then "repaired" with Adhese Universal (cured for 3 seconds) plus Tetric PowerFill (see orange bars in graph below). These values were then compared to conventional repair situations with Tetric EvoCeram Bulk Fill and Tetric EvoCeram (see red bars in graph below). "Repair" testing was carried out by adhering 2mm composite cylinder specimens to the various substrates, which had been aged for 24 hours in 37°C water.

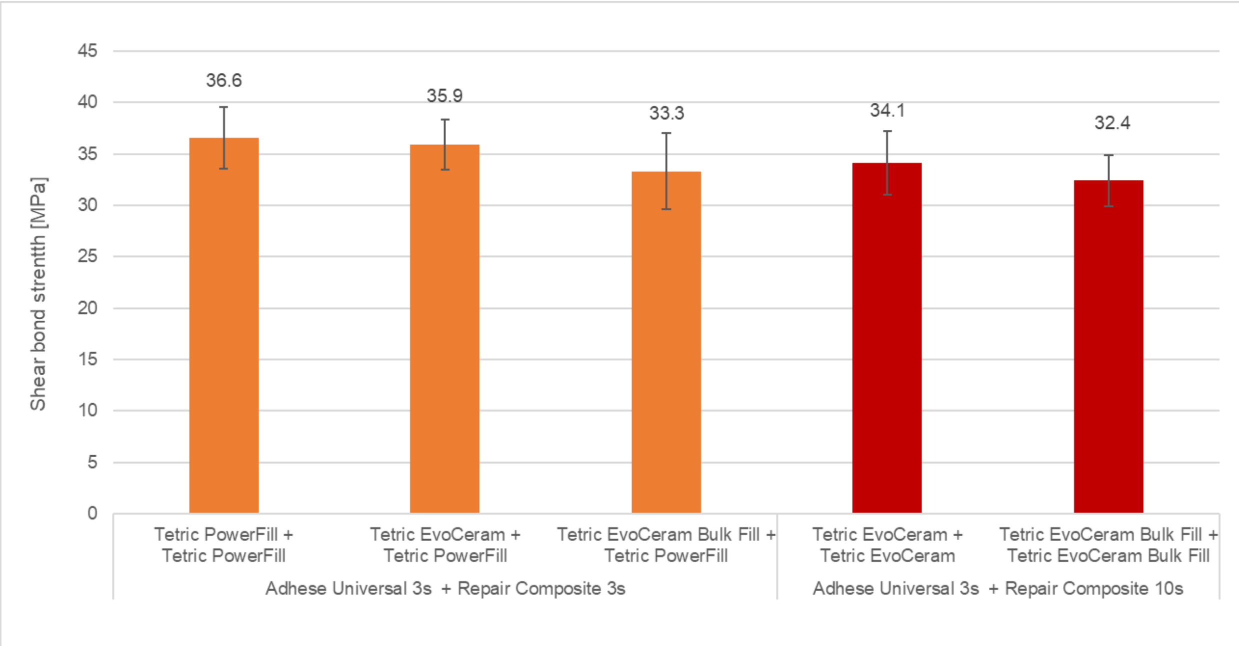


Fig. 32: Shear bond strengths after composite repair set-up with various substrates + repair materials

There was little difference between any of the composite repair set-ups. Repairing Tetric PowerFill with further Tetric PowerFill using the 3s PowerCure-Mode achieved similar results to the repair of other materials with Tetric PowerFill in 3s PowerCure-Mode and these in turn were similar to conventional repair situations with Tetric EvoCeram and Tetric EvoCeram Bulk Fill. The same test runs were also carried out with Heliobond (as a Gold Standard control) cured for 10 seconds instead of Adhese Universal cured for 3 seconds. In every case the values were higher with Adhese Universal.

5.1.3 Double-bond conversion: The shear bond strength results achieved using the 3s PowerCure-Mode (see figures 27-32), were comparable in various situations to conventional curing. This suggests that the polymerization of the adhesive and the contact zone between adhesive and composite is adequate. In order to investigate the level of cure further – the amount of double bond conversion in the adhesive was tested via FTIR spectroscopy**.** The adhesive was placed on the Golden Gate Window of the FTIR spectrometer and irradiated in 3s PowerCure-Mode from a distance of 10mm. The FTIR band of the aromatic system of the bisGMA monomer (which remains unchanged during polymerization), is integrated as an internal standard and the quotient is formed with the integral of the methacrylate signal. This procedure was repeated 30 times and the average of the calculated quotients was formed. The comparison of the average of the quotients before and after exposure allows an estimation of the double-bond turnover as a percentage of the total double-bonds present. If one double bond from every monomer reacts, this represents a double bond conversion level of 50% and the polymer chain grows. Each additional double bond reaction represents another connecting point for the 3D polymer network.

The double bond conversion in Adhese Universal when cured for 3 seconds with Bluephase PowerCure was compared to that when cured for 10 seconds with Bluephase Style.

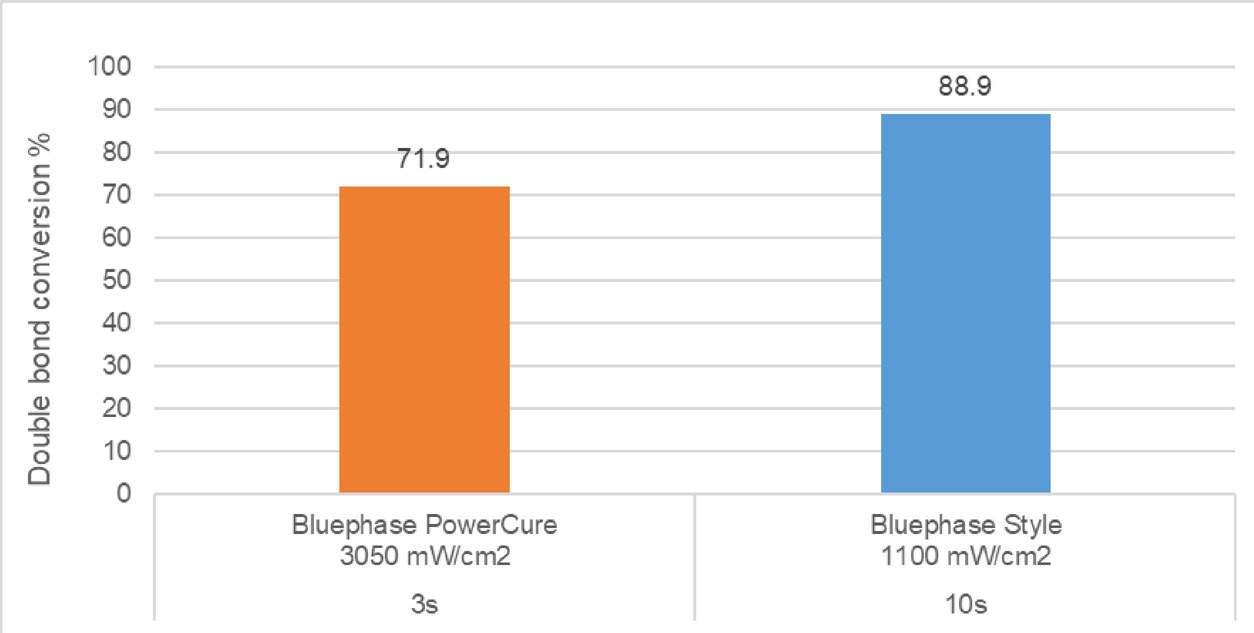


Fig. 33: Percentage double bond conversion in Adhese Universal under different curing protocols

The double bond conversion is high in both groups. After 3 second curing the percentage was somewhat lower than that after conventional curing, however the value is absolutely comparable to similar adhesives mentioned in the literature. [21]

5.1.4 Desensitization

It is generally agreed that hypersensitivity occurs due to fluid movements within the dentin tubuli in response to stimuli such as cold, warmth or osmotically active substances such as sugar.[22]
The water/ethanol solvents and the integrated micro-fillers in Adhese Universal are designed to enhance penetration into the dentin tubuli to ensure the formation of a reliable dentin seal by a homogenous adhesive layer with defined resin tags. In addition, the acidic monomers contained in Adhese Universal trigger a coagulation of the proteins in the dentinal fluid - so contributing to the mechanical sealing of the tubuli by helping to prevent fluid movement and thus postoperative sensitivity associated with that movement. A combination of thixotropic silica and carboxylic acid functionalized polymer also facilitates the uniform film-formation of Adhese Universal. Insufficient polymerization of adhesive in the dentin tubuli is viewed as a potential cause of post-operative sensitivity.

Tubuli penetration with Adhese Universal after 3-second curing was therefore investigated by adding 700ppm of a red fluorescent dye to the adhesive and applying it to bovine teeth embedded in epoxy resin. The dentin was exposed via grinding, etched for 15 seconds with phosphoric acid, rinsed and dried. The fluorescent adhesive was then applied and polymerized (according to the instructions for use) for either 3 seconds with Bluephase PowerCure or 10 seconds with Bluephase Style. The adhesive layer was then removed from specimens with a scalpel and the dentin was carefully exposed using sand paper. Residual grinding dust was removed via a 15-second phosphoric acid treatment followed by rinsing. The height of the resin cylinder was then established and the extent of the tubuli infiltration was investigated at various depths as viewed under a fluorescence microscope at a magnification of 50x.

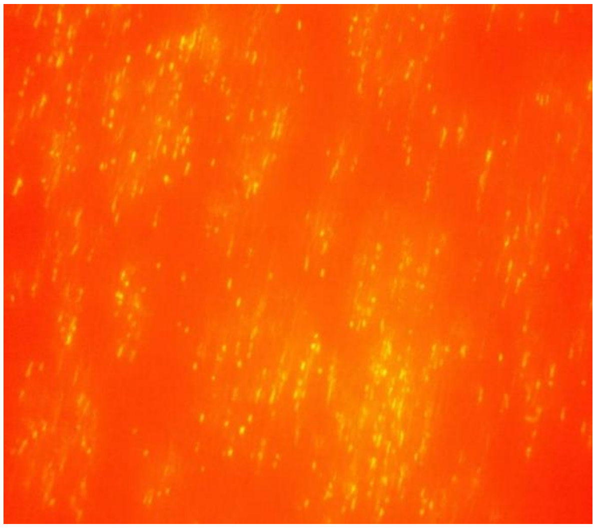


Fig. 34a: Adhese Universal penetration in bovine dentin after 10s curing at 1100mWcm^2 at 140µm

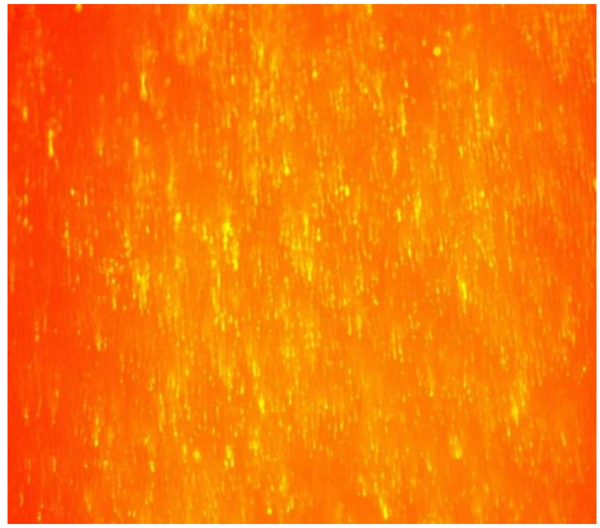


Fig. 34b: Adhese Universal penetration in bovine dentin after 3s curing at 3050mW/cm^2 at 140µm

The pictures above show the tubuli penetration (yellow sections) at a depth of 140 µm from the surface of each specimen. Similar levels of adhesive-penetration were visible in both specimens up to 200 µm. No negative effect due to the reduced curing time was found.

5.1.5 Marginal Adaptation

Marginal adaptation refers to the degree of approximation or fit of a filling material (or dental prosthetic) to the tooth surface. Marginal adaptation is affected by multiple factors – the chemical composition of the adhesive, shrinkage and shrinkage stress within the composite-material during polymerization, the size of the cavity, C-Factor, the application technique and the curing mode. Tight marginal adaptation and seal at the dentinal and enamel interfaces is largely accepted as desirable for biological, functional and esthetic reasons although there is also consensus that the clinical relevance of *in vitro* microleakage and marginal adaptation tests may be limited as actual risk is more dependent on the individual caries risk of patients.[23]

Marginal Analysis of Adhese Universal plus Tetric PowerFill restorations cured with Bluephase PowerCure. [24]

Dr. Uwe Blunck, Department of Operative and Preventive Dentistry, Charité Universitätsmedizin, Berlin Germany (2018)

Objective: To evaluate the quality of the margins produced when using the 3s PowerCure material-system together with the Bluephase PowerCure curing light in 3s PowerCure-Mode.

Method: Class V cavities were prepared at the cervical edge of extracted human incisors. Although Class V restorations are not indicated for the 3s PowerCure-System - for the purposes of *in vitro* marginal analysis, such a tooth model is suitable.

Tetric PowerFill bulk fill restorations were compared to Tetric EvoCeram restorations – both placed in one layer. Eight incisors were evaluated for each group as shown in the table below. Both the Etch & Rinse (E&R) technique and the Self-Etch (SE) technique were evaluated with each composite according to the instructions for use.

Adhese Universal		Adhese Universal	
Etch & Rinse	Self-Etch	Etch & Rinse	Self-Etch
Tetric EvoCeram		Tetric PowerFill	
Bluephase Power Cure High 10s (1200mW/cm^2)		Bluephase Power Cure 3s PowerCure-Mode (3050mW/cm^2)	
n=8	n=8	n=8	n=8

Table 6: Experimental groups comparing marginal adaptation of Tetric PowerFill and Tetric EvoCeram restorations

The oval cavities were approximately 3mm long mesially-distally, 4mm high (incisal-apical direction) and 1.5mm deep. Placed cervically, the cavities encompassed both enamel and dentin surfaces.

Fig 35a: Extracted filled tooth

Fig 35b: Gold-coated replica tooth

After finishing and polishing to avoid any overhangs, the incisors were stored in water for 21 days and then subjected to 2000 cycles of thermocycling (5-55°C). Replicas were made from each specimen, using impression material, which was then filled with expoxy resin and coated with gold film. Gold-coated replicas were prepared before and after thermocycling for quantitative marginal analysis via scanning electron microscope (200x). The marginal quality was evaluated according to four defined levels: 1: continuous (hardly discernable) margins, 2: marginal irregularities, 3: hairline cracks, 4: severe gaps.

Results in dentin: The following graph shows the amount of continuous margin in dentin as a percentage of the entire marginal length i.e. the percentage of margin that was rated 1 as defined above.

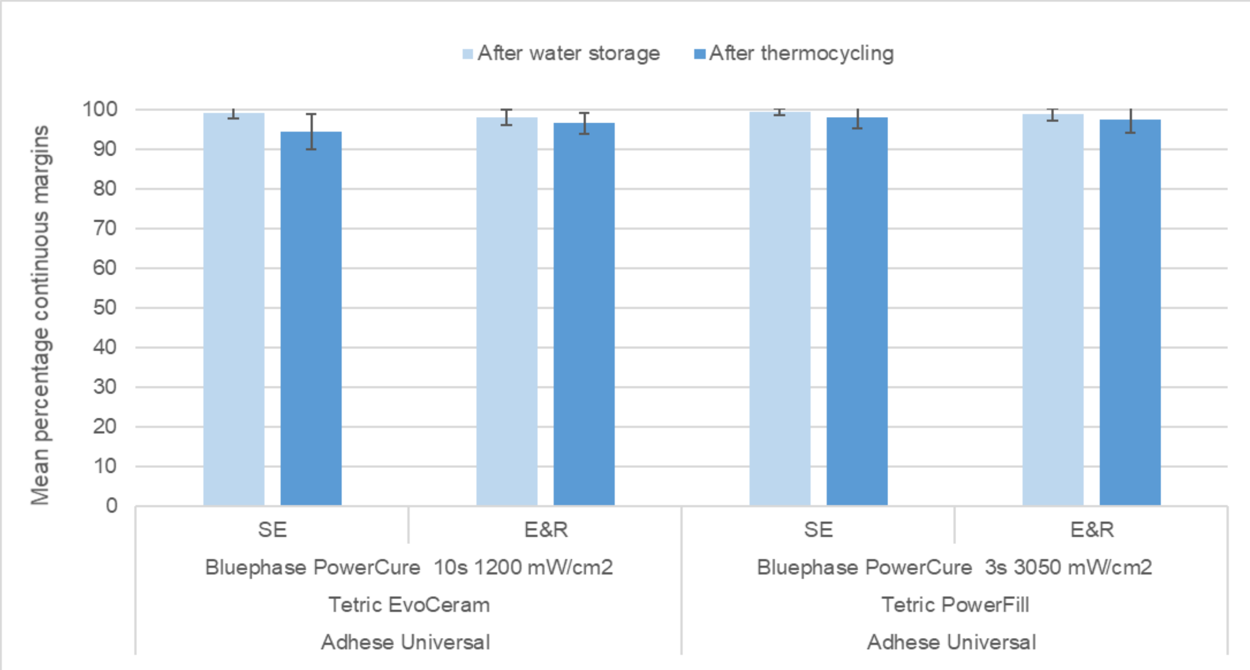
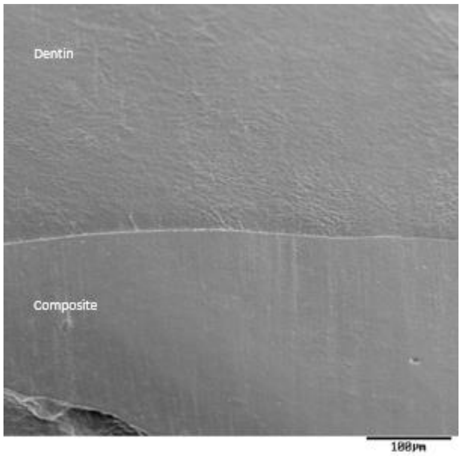


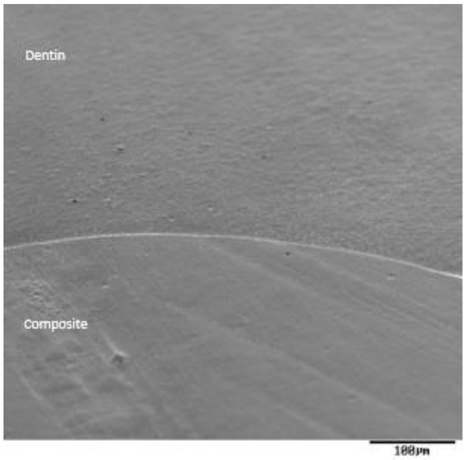
Fig 36: Percentage of continuous margin for Tetric EvoCeram and Tetric PowerFill in dentin with different etching and curing techniques

The mean percentages exhibiting "perfect" continuous margins (Rating =1) ranged between 94% and 99%, with the lowest percentage occurring in the Tetric EvoCeram (SE) group. No margin sections were rated lower than 2. The differences after thermocycling were minimal. There was no statistical difference between the groups (comparing the same etching technique) after thermocycling and no statistically significant difference between the etching techniques for each composite. In comparison to previous studies (by the author) carried out with Adhese Universal and Tetric EvoCeram (in increments) or Tetric EvoCeram Bulk Fill, there was also no statistically significant difference.

Tetric EvoCeram (SE)

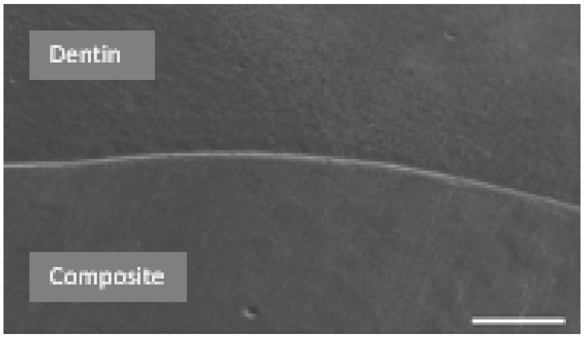


Tetric PowerFill (SE)

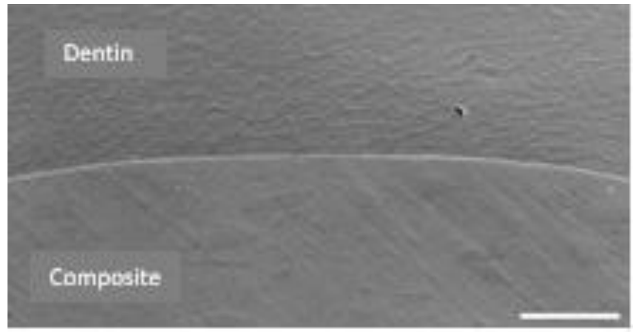


Figs. 37a-b: Comparison of continuous margins in dentin of Tetric EvoCeram and Tetric PowerFill restorations: Self-Etch technique. SEM 200x, Bar = 100µm

Tetric PowerFill (E&R)



Tetric PowerFill (SE)



Figs. 38a-b: Comparison of continuous margins in dentin of Tetric PowerFill according to different etch techniques. SEM 200x, Bar = 100µm

The SEM photographs above show examples of the very similar continuous margins found in dentin after thermocycling. The first two photographs compare Tetric EvoCeram and Tetric PowerFill (SE group) and the second two compare the different etching techniques on Tetric PowerFill.

Results in enamel: The following graph shows the amount of continuous margin in enamel as a percentage of the entire marginal length i.e. the percentage of margin that was rated 1 as defined above.

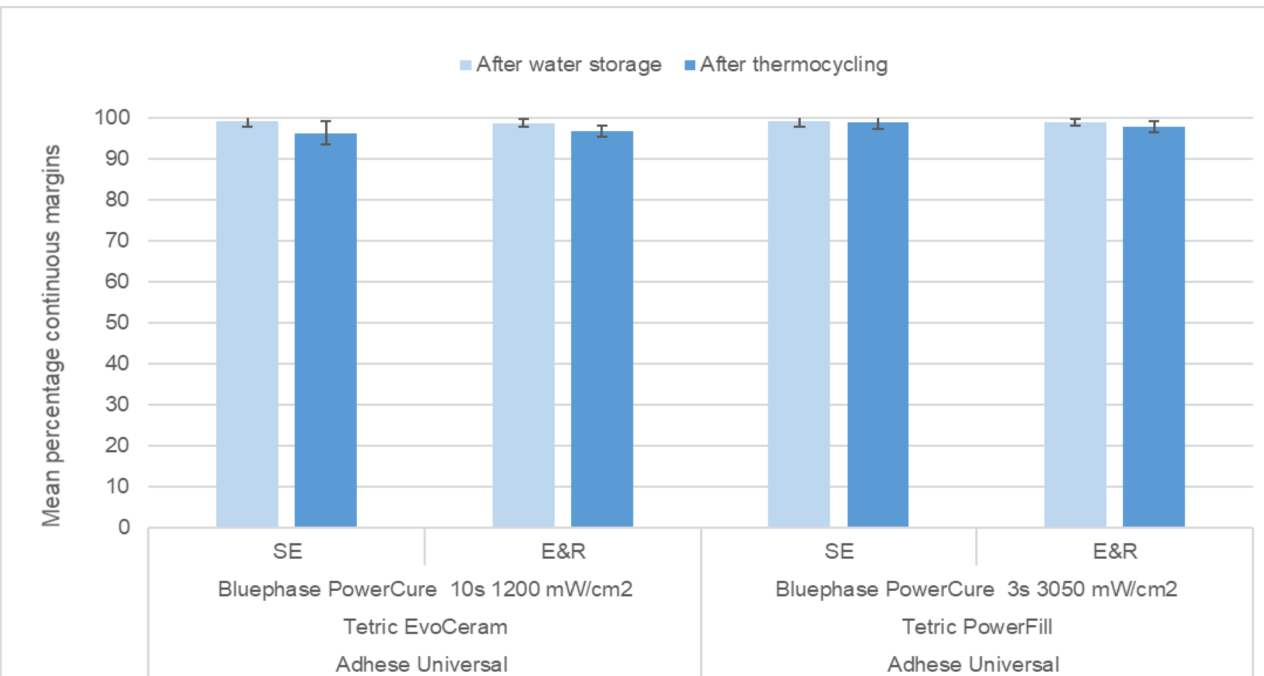
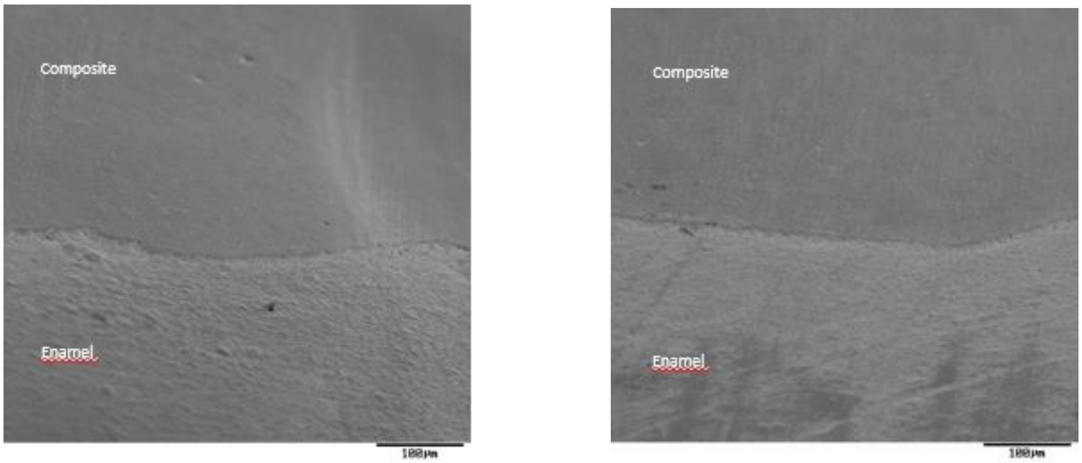


Fig 39: Percentage of continuous margin for Tetric EvoCeram and Tetric PowerFill in enamel with different etching and curing techniques

The mean percentages exhibiting "perfect" continuous margins (Rating =1) ranged between 96% and 99%, with the lowest percentage occurring in the Tetric EvoCeram (SE) group. No margin sections were rated lower than 2. The differences after thermocycling were minimal. There was no statistical difference between the groups (comparing the same etching technique) after thermocycling and no statistically significant difference between the etching techniques for each composite.

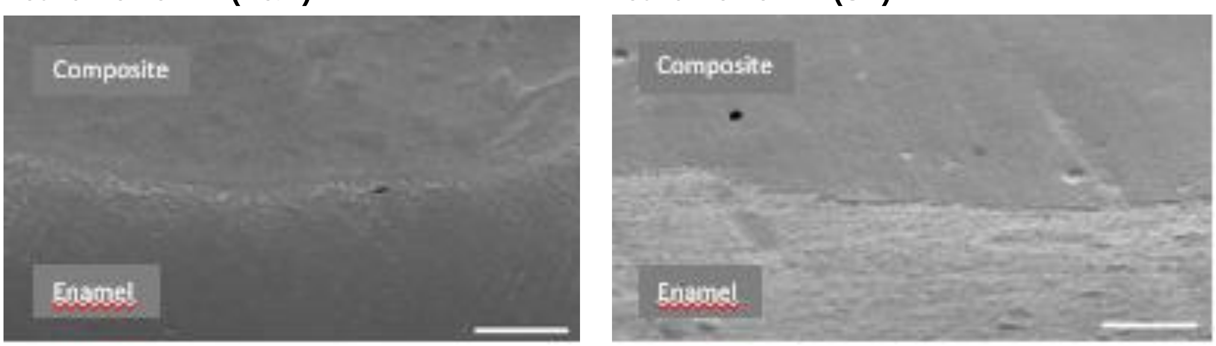
The SEM photographs below show examples of the very similar continuous margins found in enamel after thermocycling. The first two photographs compare Tetric EvoCeram and Tetric PowerFill (SE group) and the second two compare the different etching techniques of Tetric PowerFill.

Tetric EvoCeram (SE) **Tetric PowerFill (SE)**



Figs. 40a-b: Comparison of continuous margins in enamel of Tetric EvoCeram and Tetric PowerFill restorations: Self-Etch technique. SEM 200x, Bar = 100µm

Tetric PowerFill (E&R) **Tetric PowerFill (SE)**



Figs. 41a-b: Comparison of continuous margins in enamel of Tetric PowerFill according to different etch techniques. SEM 200x, Bar = 100µm

Conclusion: The results of the study indicate that the 3s PowerCure-System (Adhese Universal and Tetric PowerFill cured with Bluephase Power Cure in 3s PowerCure-Mode) is effective in terms of marginal adaptation in both dentin and enamel and with SE or E&R etching techniques.

There was no statistically significant difference between the Tetric EvoCeram or Tetric PowerFill groups. The short curing time and high light intensity still resulted in very high percentages of margin rated as continuous in both dentin and enamel.

5.2 Investigations with Tetric PowerFill & Tetric PowerFlow

Curing composites
The principle indication of curing lights is the polymerization of composite restoratives. The degree of cure is dependent upon a number of parameters, light intensity being one of the most important (see Section 2.4). The efficiency of the light curing of composites can be verified by examining various properties of the polymerized material. Resin based materials/composites change their hardness, flexural strength and modulus of elasticity during polymerization. The depth of cure of composites is directly related to the light power of the curing light and spectroscopic methods (e.g. infrared spectroscopy) can be used to determine the chemical conversion of the monomers used.

Depth of cure and shrinkage
Both depth of cure and polymerization shrinkage are particularly important clinical parameters for bulk fill composites. Excessive polymerization shrinkage can lead to open margins, microleakage cuspal deflection, enamel fracture and post-operative sensitivity. Inadequate depth of cure could also leave composite at apical margins soft and susceptible to wear, dissolution or fracture.

Establishing depth of cure
Determining *in vivo* whether or not a composite is completely cured is problematic. The uppermost layer is seen to be hard, however deeper layers are invisible and may remain unpolymerized. In general, the more translucent and lighter coloured a composite the greater the light penetration and therefore depth of cure. There are a number of ways to establish depth of cure (*in vitro*) in dental materials.

The international standard ISO 4049 for polymer based restorative materials suggests measuring depth of cure via preparing cylindrical specimens 6 mm long and 4 mm wide, or if a depth of cure greater than 3 mm is claimed, the length should be at least 2 mm 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 polymerization.

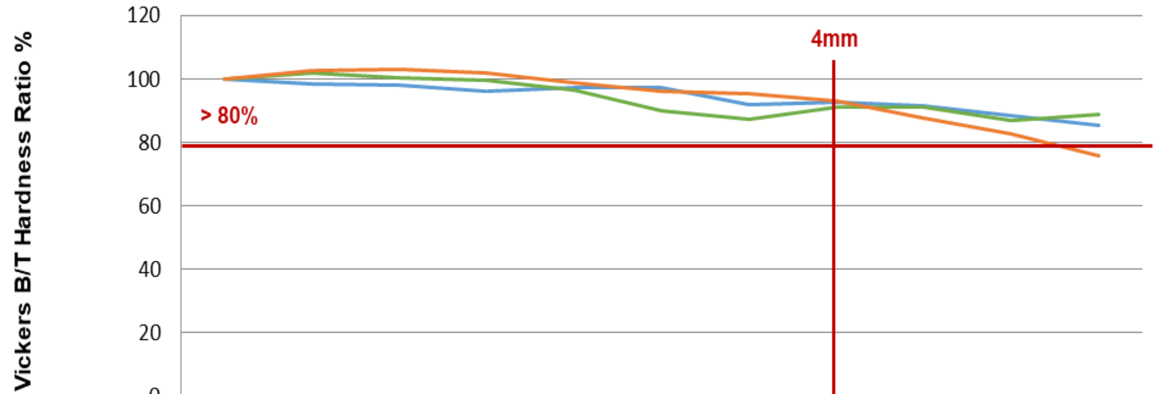
Alternatively, Vickers hardness (utilizing a square-diamond pyramid indenter) and Knoop hardness profiles (utilizing an elongated – diamond pyramid indenter) of the cured material, are also suitable for determining depth of cure. Cured specimens are usually prepared in cylindrical moulds and the hardness at the top and bottom of the cylinder is measured. 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%.[25] In a study by Professor David Watts of the University of Manchester, UK, an acceptable depth of cure was considered achieved when the bottom hardness corresponded to at least 80% of the surface hardness.[26] This value has become an accepted threshold for measuring and comparing depth of cure. Several studies have determined that bulk-fill composites achieve this degree of conversion at a depth of 4mm.[27-29]

The following internal investigations confirm adequate depth of cure at a depth of 4mm with Tetric PowerFill and Tetric PowerFlow.

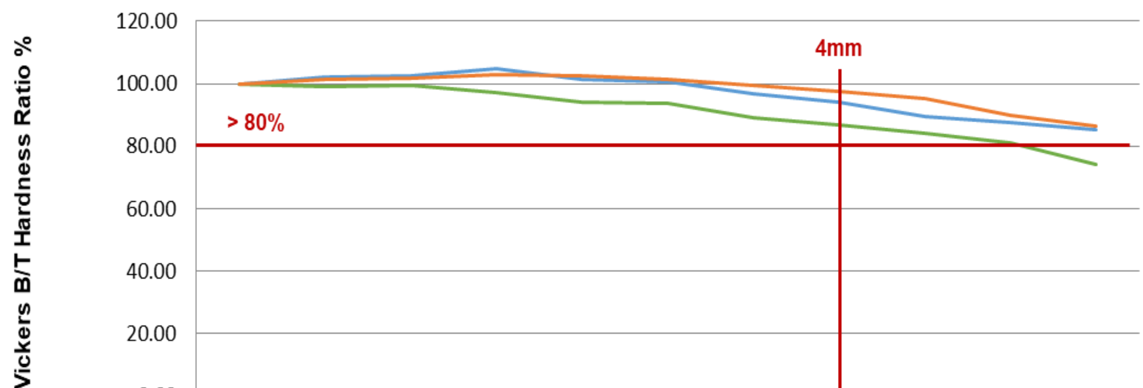
5.2.1 Vickers Hardness

Vickers hardness B/T ratio: All shades of Tetric PowerFill & Tetric PowerFlow
The Vickers hardness (VH) was investigated in Tetric PowerFill and Tetric PowerFlow specimens that had been cured for 3 seconds with Bluephase PowerCure in 3s PowerCure-Mode. The results at various depths (up to 5.5mm) are shown as a percentage of the surface, in the graphs below.



	0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm
Tetric PowerFill IVA	100	98.54	97.91	96.29	97.14	97.27	91.8	92.65	91.51	88.3	85.48
Tetric PowerFill IVB	100	101.76	100.38	99.45	96.68	89.84	87.37	91	91.21	87.06	88.77
Tetric PowerFill IVW	100	102.55	103.15	101.86	98.81	96.25	95.53	93.05	87.82	82.82	75.92

Fig. 42: Bottom/top Vickers hardness ratios at 0.5mm intervals for each of the Tetric PowerFill shades



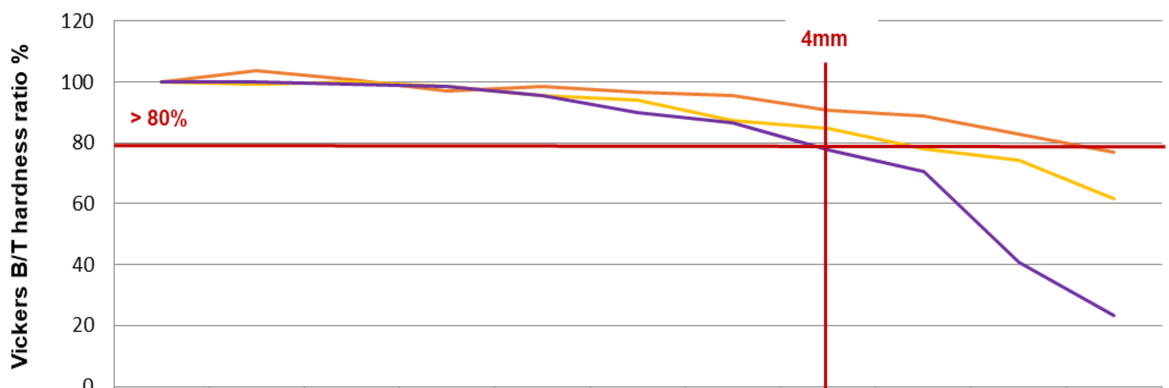
	0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm
Tetric PowerFlow IVA	100.00	102.15	102.60	104.82	101.33	100.56	96.95	93.90	89.49	87.46	85.27
Tetric PowerFlow IVB	100.00	98.91	99.26	97.00	94.19	93.62	89.27	86.75	84.20	81.01	74.03
Tetric PowerFlow IVW	100	101.37	101.85	102.86	102.37	101.29	99.47	97.36	95.22	89.85	86.59

Fig. 43: Bottom/top Vickers hardness ratios at 0.5mm intervals for each of the Tetric PowerFlow shades

It can be seen that at a 4mm depth (the maximum recommended increment depth for the Tetric Power Fill/Flow composites), the ratio well exceeds the 80% threshold for all shades of both materials. The 80% threshold is in fact exceeded up to 5mm for all shades – falling below 80% at 5.5mm for the IVW shade of Tetric PowerFill and for the IVB shade of Tetric PowerFlow. The VH values at 4mm for Tetric PowerFill also exceeded the percentages attained with the proven bulk fill product Tetric EvoCeram Bulk Fill (IVA 86%, IVB 85%, IVW 88%), when cured for 10 seconds with Bluephase Style in an identical investigation.

Vickers Hardness B/T ratio: Various curing distances with Tetric Power Fill

The bottom/top Vickers hardness ratio was also investigated with regard to curing distance – i.e. the gap between the light tip and the composite to be cured. The graph below shows the VH ratio for Tetric PowerFill in shade IVA (after 3 second curing with Bluephase PowerCure). The IVA shade represents the worst case scenario, from a polymerisation standpoint, as containing the most pigments it is the least translucent in terms of light transfer. The threshold of 80% for 4mm increments is exceeded up to a distance/gap of 6mm and is almost reached at a gap of 8mm.

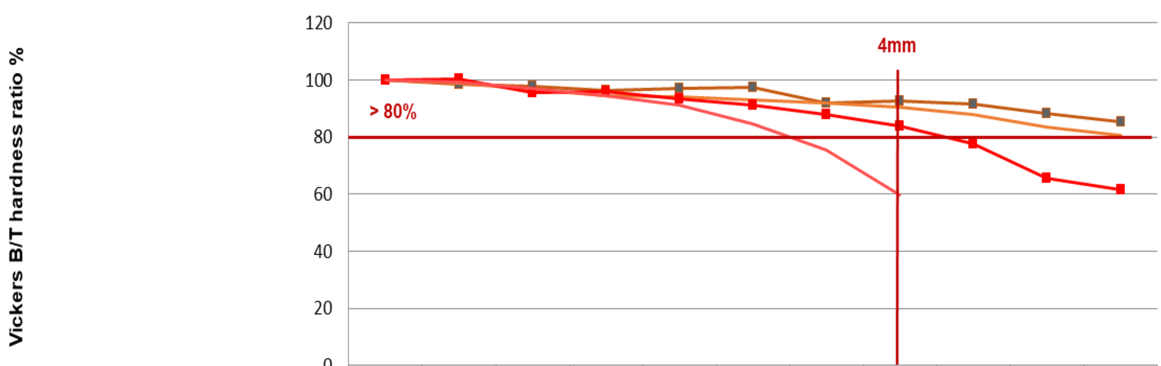


	0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm
No gap	100	103.58	100.93	97.11	98.6	96.75	95.4	90.86	88.93	83.01	77.05
6mm gap	100	99.43	100.08	98.38	95.38	94.21	87.19	84.92	77.99	74.3	61.61
8mm gap	100	100.06	99.36	98.34	95.71	90.02	86.62	77.79	70.43	40.74	23.27

Fig. 44: Bottom/top Vickers hardness ratios at 0.5mm intervals for Tetric PowerFill IVA shade with various curing distances. R&D Ivoclar Vivadent

Vickers hardness B/T ratio: 3s & 10s curing

The graph below shows the bottom/top Vickers hardness ratio for Tetric PowerFill (IVA) when cured conventionally for 10 seconds and for 3s in PowerCure-Mode. It also compares the product to Tetric EvoCeram Bulk Fill (IVA) and Tetric EvoCeram (A3).



	0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm
Tetric PowerFill (3s: 3050mW/cm2)	100	98.54	97.91	96.29	97.14	97.27	91.8	92.65	91.51	88.3	85.48
Tetric PowerFill (10s: 1100mW/cm2)	100	98.92	96.82	94.63	94.03	93.01	91.87	90.49	87.96	83.51	80.69
Tetric EvoCeram Bulk Fill (10s: 1100mW/cm2)	100	100.22	95.45	95.87	93.29	91.16	87.89	83.83	77.82	65.47	61.56
Tetric EvoCeram (10s: 1100mW/cm2)	100	99.27	97.22	94.46	91.21	84.56	75.35	59.92			

Fig. 45: Bottom/top Vickers hardness ratios at 0.5mm intervals for Tetric PowerFill, Tetric EvoCeram Bulk Fill and Tetric EvoCeram. R&D Ivoclar Vivadent

It can be seen that the method of cure (3s or 10s) has little bearing on the resulting hardness ratios for Tetric PowerFill and in both cases the 80% threshold is well exceeded at a depth of 4mm. Tetric PowerFill achieves higher values than Tetric EvoCeram Bulk Fill with both curing modes and at 4mm the levels reached (>90%) are similar to the level reached by Tetric EvoCeram (an incremental material) at the 2mm level.

It should also be noted that the initial top values whereby the 100% level is set are similar for all the materials. Clearly 80% of a poor surface value is not a reassuring result. Each of the materials noted in the graph above exhibit a mean top surface (at 0.5mm) hardness of between 620 and 690 MPa.

5.2.2 Double bond conversion

To further investigate cure/polymerization, the amount of double bond conversion in the composites was tested using FTIR spectroscopy. The restorative materials were placed on the crystal of the ATR unit of the FTIR spectrometer. The material was condensed in a mould of a specific height, the surface was covered with a PE strip and irradiated for the defined curing time with the corresponding curing unit. The FTIR band of the aromatic reference bonds of the bisGMA monomer (which remain unchanged during polymerization), are integrated as an internal standard and the quotient is formed with the integral of the methacrylate signal. This procedure was repeated 30 times and the average of the calculated quotients was formed. The comparison of the resulting quotients before and after exposure, allows an estimation of the double-bond turnover in percent. If one double bond of every bi-functional monomer (meaning two methacrylate functions are available per monomer) reacted in a linear polymer chain, a double bond conversion of 50% would be achieved. Every reaction of the second available double bond of the bi-functional monomers acts as a connection point (cross-link) in the final 3D polymer network. There is no 100% conversion of every available double bond of each bi-functional monomer, because not every available "first" double bond reacts in a linear polymer chain. Due to space-hindrance it is also not possible for every second available double bond to establish a cross-link in the polymer network. Therefore, double bond conversion values of between 40 and 70% (depending on the matrix) are common. The values for flowable materials are usually higher, as their matrix comprises mono-functional monomers. They have no second methacrylate function, therefore the relation between the aromatic reference double bonds and the reacted methacrylates is higher.

The graph below shows 4mm increments of Tetric PowerFill when cured for 3 or 10 seconds with Bluephase PowerCure in 3s PowerCure-Mode and High mode respectively and also compared to a 2mm increment of Tetric EvoCeram when cured conventionally. Similarly, on the right of the graph the flowable Tetric PowerFlow is compared in different curing modes and with Tetric EvoFlow.

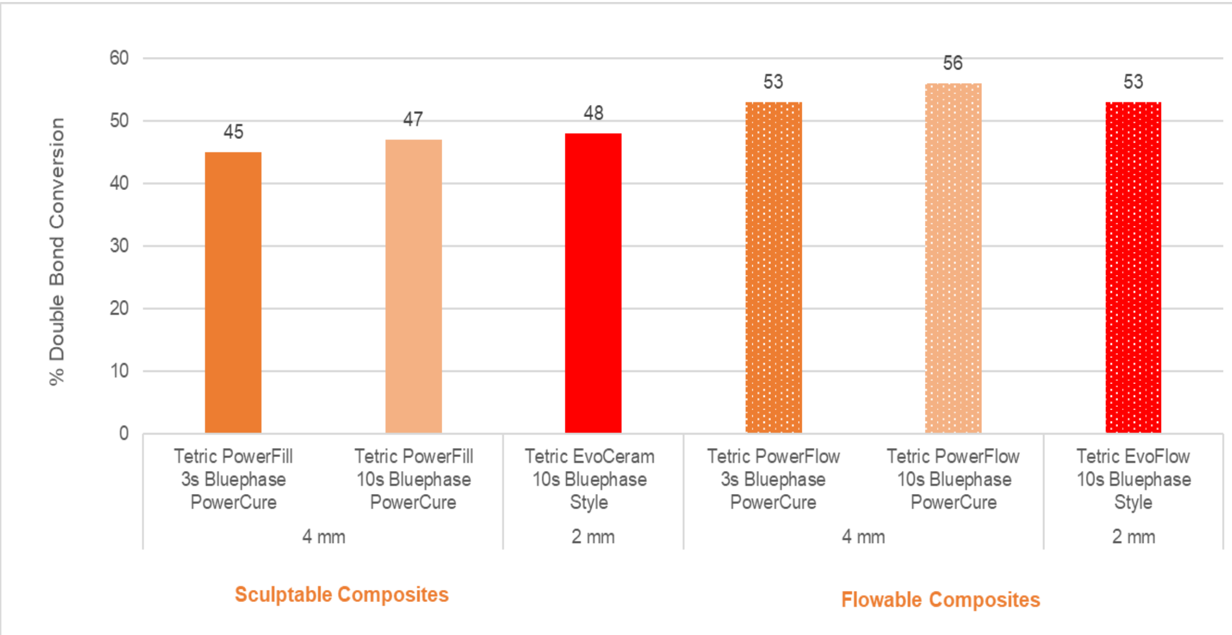


Fig. 46: Double bond conversion in Tetric PowerFill and Tetric PowerFlow with different curing protocols and compared to conventional composites.

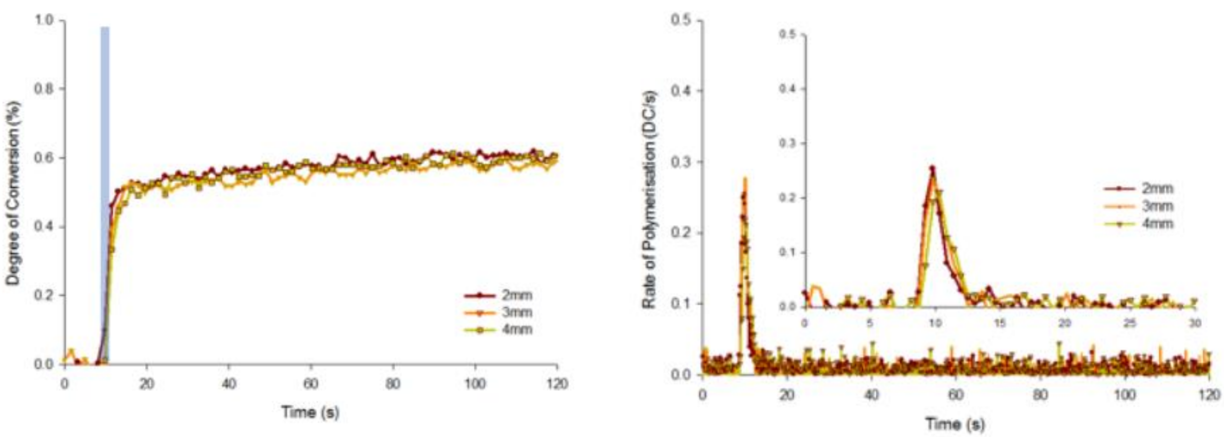
The values are all very similar within each composite group (sculptable or flowable) i.e. Tetric PowerFill does not differ noticeably when cured for 3 or 10 seconds and the degree of conversion is similar to that achieved with a thinner increment of the well-established composite Tetric EvoCeram. A very similar picture albeit at a slightly higher level (due to the higher monomer content of flowables) is seen with Tetric PowerFlow. The 3s PowerCure-Mode is shown not to differ substantially from 10 second curing or from the amount of conversion expected in traditional composites.

Degree of conversion: 3s PowerCure-Mode vs. conventional curing[30]

W. Palin, University of Birmingham, United Kingdom (2018)

Palin et al from the University of Birmingham, UK, also investigated the degree of conversion in samples of Tetric PowerFill, Tetric PowerFlow, when cured using the Bluephase PowerCure in 3s PowerCure-Mode (3050 mW/cm^2) and when cured conventionally with Bluephase Style (1200 mW/cm^2) for 10 seconds. The degree of conversion was measured at the lower surface of 2, 3 and 4 mm specimens of the two materials using absorption spectroscopy ATR (MCT detector). The light curing time is illustrated by the light blue column in the diagrams on the left.

Tetric PowerFill cured with Bluephase PowerCure in 3s PowerCure-Mode



Tetric PowerFill cured with Bluephase Style for 10s

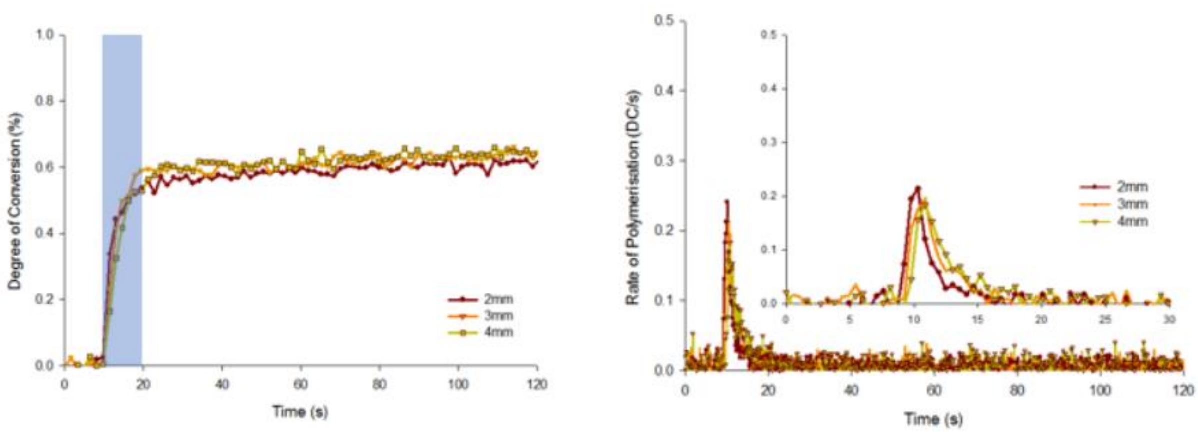
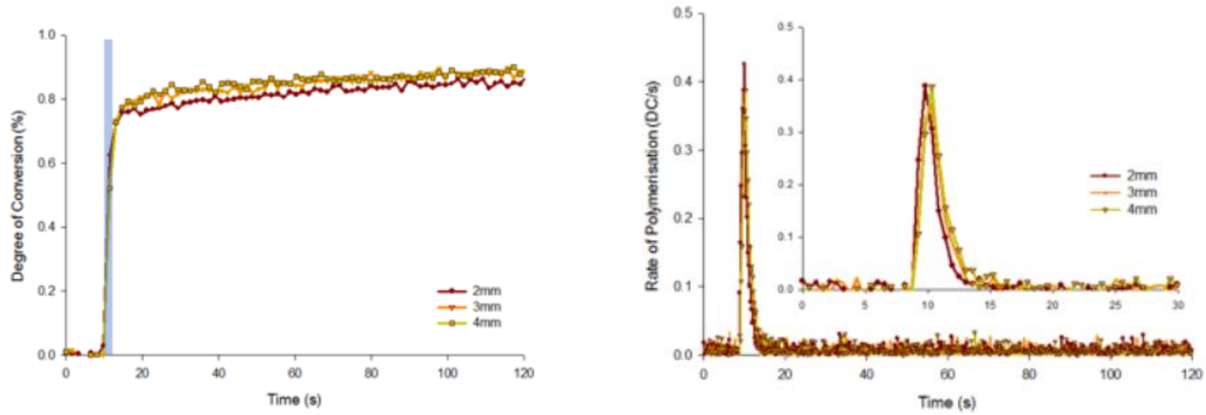


Fig 47 a-d: Degree of conversion for Tetric PowerFill when cured with Bluephase PowerCure (top diagrams) or conventionally with Bluephase Style (bottom diagrams). *Palin, Birmingham University, UK*

The degree of conversion pattern for the sculptable composite Tetric PowerFill is very similar for all depths of composite with both Bluephase PowerCure (3s) and Bluephase Style (10s).

Tetric PowerFlow cured with Bluephase PowerCure in 3s PowerCure-Mode



Tetric PowerFlow cured with Bluephase Style for 10s

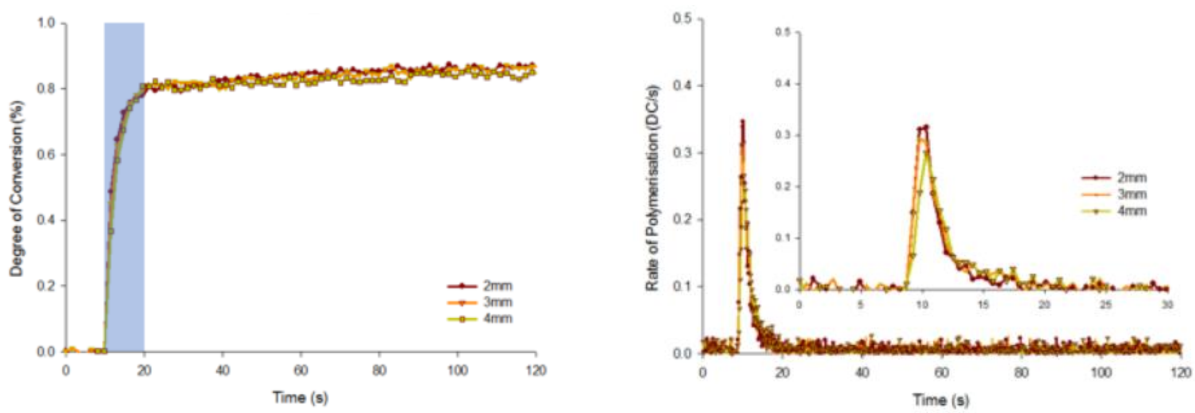


Fig 48a-d: Degree of conversion for Tetric PowerFlow when cured with Bluephase PowerCure (top diagrams) or conventionally with Bluephase Style (bottom diagrams). *Palin, Birmingham University, UK*

As with the sculptable composite the degree of conversion pattern for the flowable composite Tetric PowerFlow is very similar for all depths of composite and the pattern is largely identical to that arising from conventional curing.

Degree of conversion: 3s PowerCure-Mode vs. conventional curing [31]

N. Ilie, University of Munich, Germany

Nicoleta Ilie of the University of Munich also measured the degree of conversion using ATR-FTIR (Fourier Transform Infrared Spectroscopy) in 2mm and 4mm specimens of Tetric PowerFill when cured with the Bluephase PowerCure in 3s PowerCure-Mode or conventionally in High mode for 10s (1200 mW/cm^2) and Tetric EvoCeram Bulk Fill, also cured in High mode (10s).

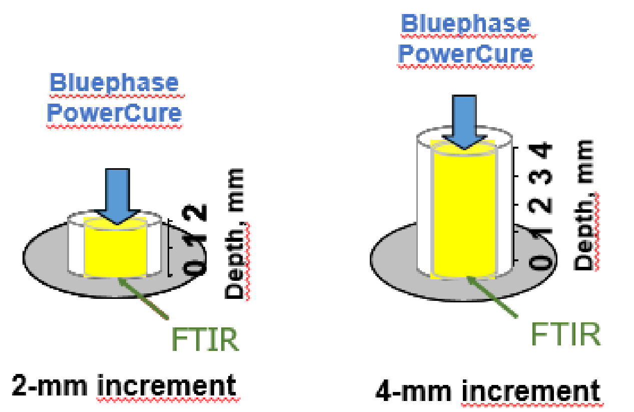


Fig. 49: Schematic representation of testing set-up for measuring degree of conversion. *Ilie, University of Munich, Germany* [31]

There was no significant difference (all p values > 0.05) between the 2mm and 4mm samples within any group.

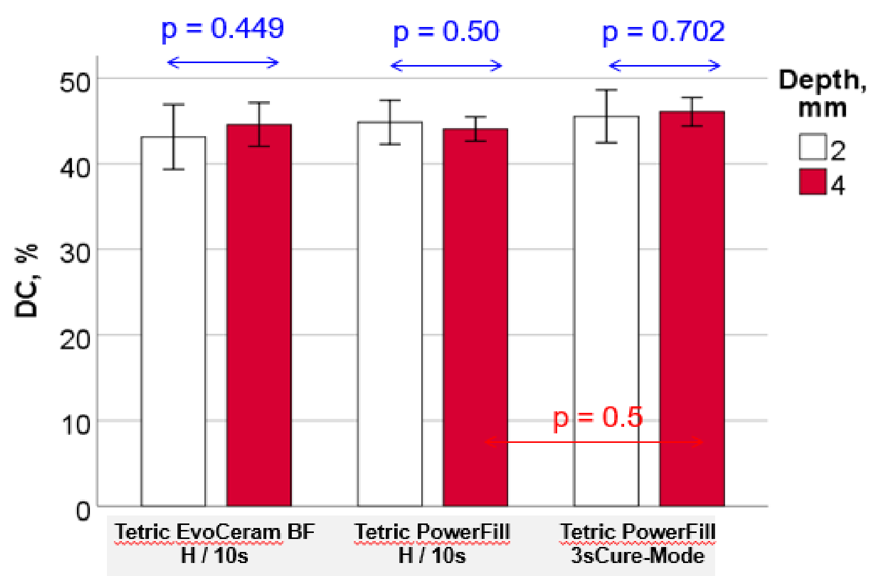


Fig. 50: Degree of Conversion in 2mm and 4mm samples. Ilie, University of Munich, Germany [31]

There was also no significant difference between the depth of cure in the 4mm sample of Tetric PowerFill when cured in 3s PowerCure-Mode compared to conventional curing. That is both curing modes resulted in similar curing results in terms of degree of monomer conversion.

5.2.3 Shrinkage

It has long been accepted that placing and curing composite restorations in 2mm increments, in some way prevents the undesirable effects of polymerization shrinkage. Three main factors are involved – the use of a small volume of material, a lower cavity configuration factor, and minimal contact with the opposing cavity walls during polymerization. It is widely accepted that incremental filling decreases shrinkage stress as a result of reduced polymerization material volume. Each increment is compensated by the next, and the consequence of polymerization shrinkage is less damaging since only the volume reduction of the last layer can damage the bond surface.[32]

Minimizing shrinkage stress in a material that is applied in bulk is therefore particularly important and this is achieved in both Tetric PowerFill and Tetric PowerFlow in part by the inclusion of a shrinkage stress reliever with a low modulus of elasticity (see section 2.2) The volumetric shrinkage (as investigated according to the Archimedes buoyancy technique) and shrinkage force (as investigated with a Bioman shrinkage stress measuring device), are depicted for Tetric Power Fill and Tetric Power Flow below.

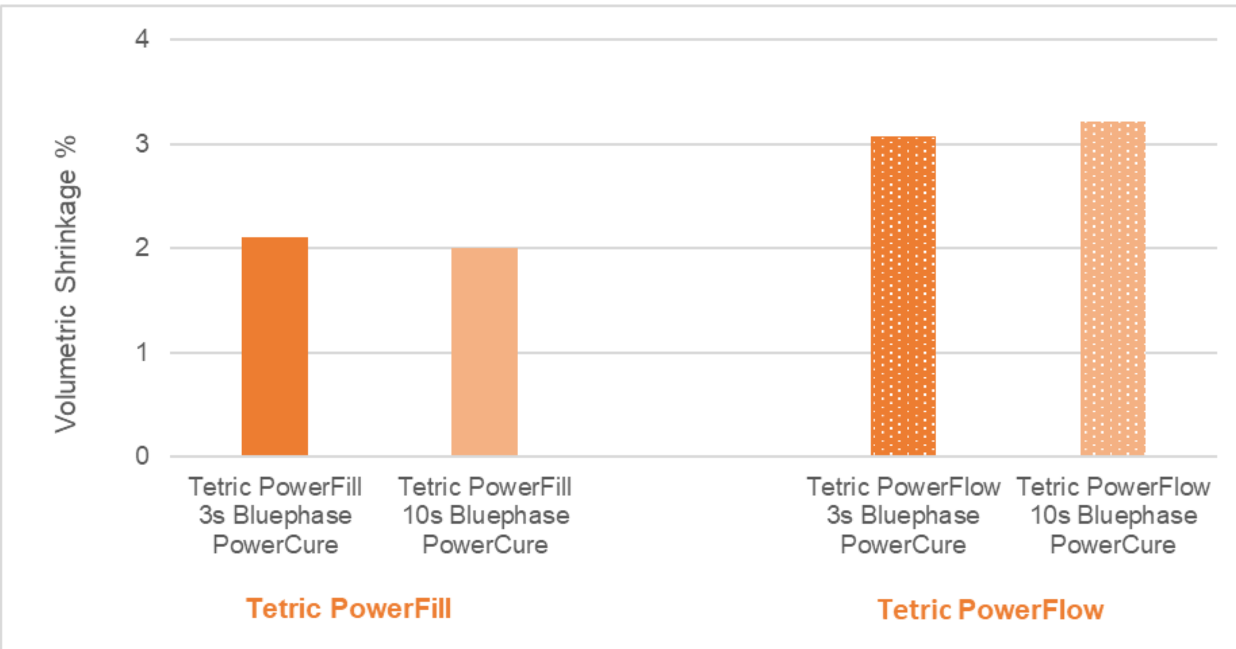


Fig. 51: Volumetric shrinkage of Tetric PowerFill and Tetric PowerFlow when cured for 3 (3050mW/cm^2) or 10 seconds (1200mW/cm^2) with Bluephase PowerCure

Curing for 3 or 10 seconds with Bluephase PowerCure had no noticeable effect on volumetric shrinkage in either Tetric PowerFill or Tetric PowerFlow. As would be expected shrinkage is somewhat higher in the flowable composite due to the higher monomer and lower filler content.

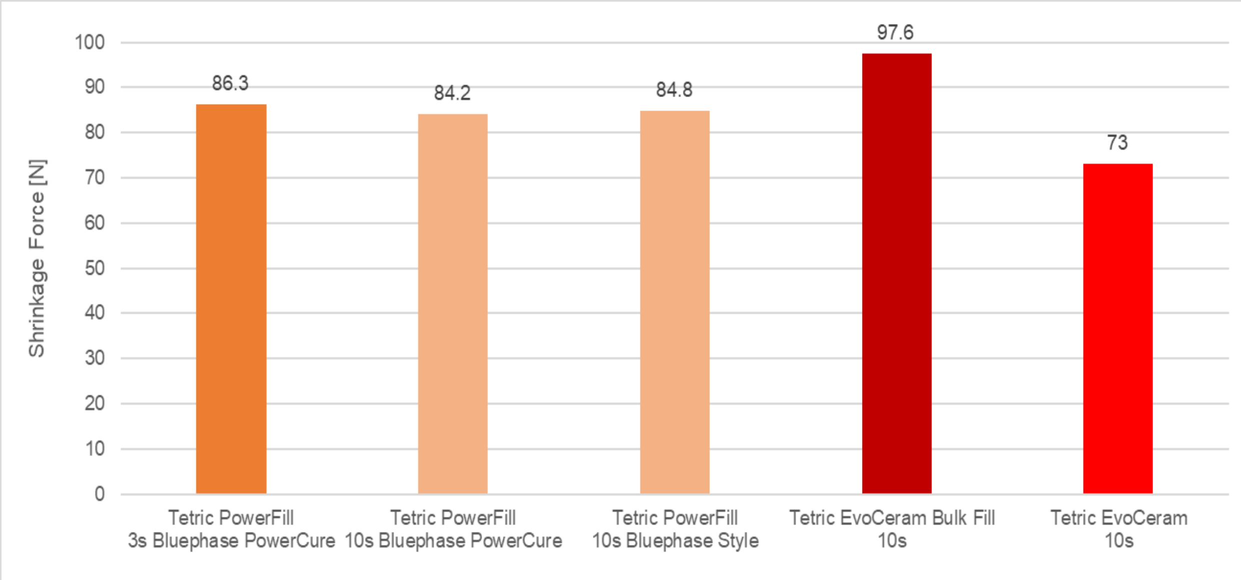


Fig. 52: Shrinkage force for Tetric PowerFill with various curing protocols compared to Tetric EvoCeram Bulk Fill and Tetric EvoCeram

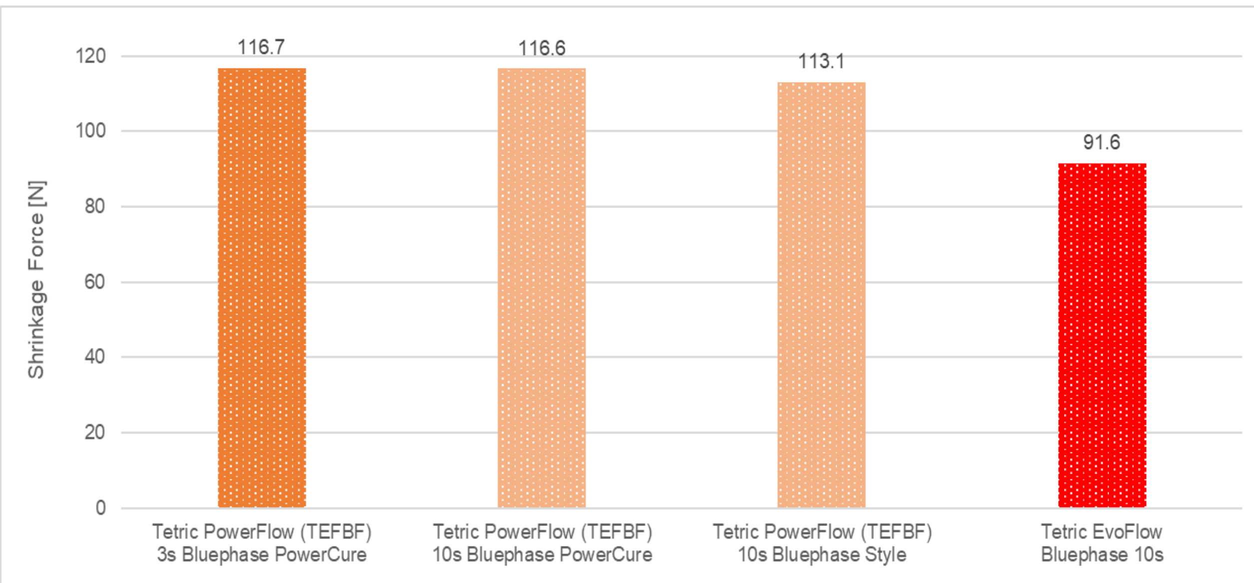


Fig. 53: Shrinkage force for Tetric PowerFlow (TEFBF) with various curing protocols compared to Tetric EvoFlow

Due to the higher monomer content, the amount of shrinkage in the flowable composites (see figure 53) exceeds that of the sculptable (see figure 52) however shrinkage is largely identical for Tetric PowerFill regardless of how it is cured and exhibits lower shrinkage force than the established bulk fill product Tetric EvoCeram Bulk Fill after 10 second curing. Tetric PowerFlow which is identical to Tetric EvoFlow Bulk Fill (TEFBF) also exhibited virtually identical shrinkage force values regardless of how it was cured.

5.2.4 Flexural Strength

Flexural strength is a measure of the performance of a composite. Clearly, a composite must be adequately polymerized to achieve adequate flexural strength. The ISO Standard 4049 for polymer based restorative materials requires that the flexural strength exceed 80 MPa.

The results of investigations conducted internally regarding flexural strength are presented below. Samples (2 x 2 x 25mm) of each of the Tetric PowerFill shades (n=5 per shade) were polymerized for either 3 seconds with the Bluephase PowerCure curing light in 3s PowerCure-Mode (3050mW/cm^2) or for 10 seconds in High mode (1200mW/cm^2).

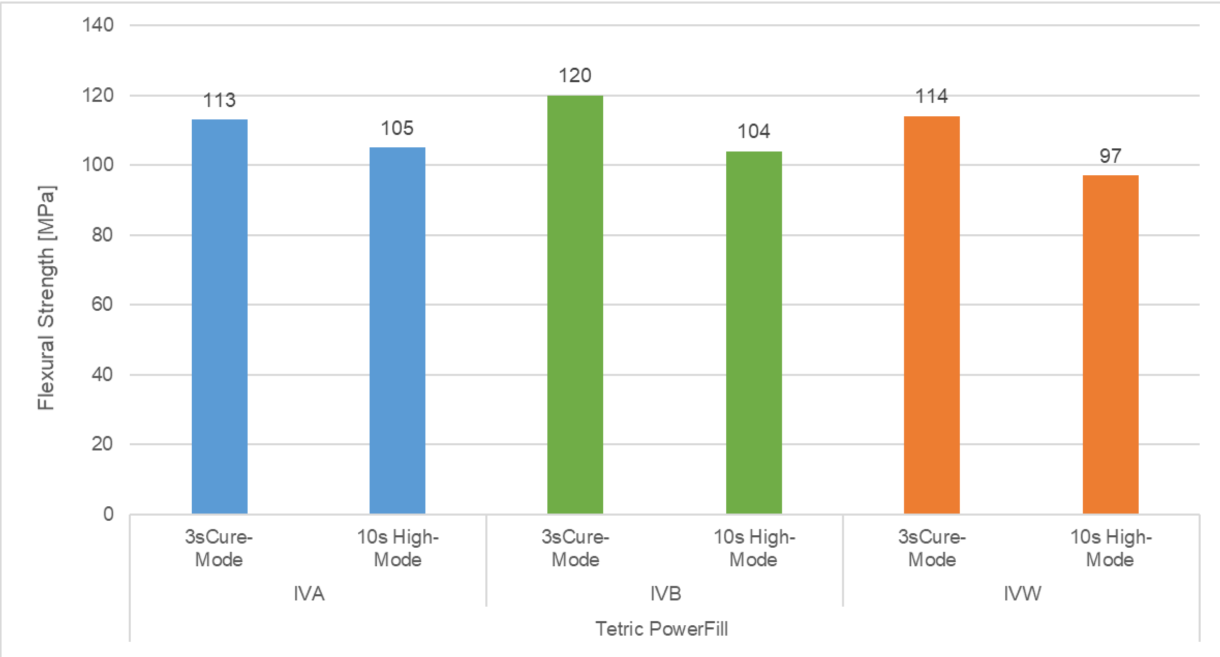


Fig. 54: Mean flexural strength of all shades of Tetric PowerFill when cured for 3 versus 10 seconds

The graph shows that the flexural strengths were similar in both curing modes and those attained after 3 second curing actually exceeded those with 10 second curing.

The flexural strengths of Tetric PowerFill and Tetric PowerFlow (the same as Tetric EvoFlow Bulk Fill: TEFBF) when cured in 3s PowerCure-Mode with Bluephase PowerCure (3050mW/cm^2) were also compared to a 10 second curing time with Bluephase Style (1200mW/cm^2) and the incremental composites Tetric EvoCeram and Tetric EvoFlow respectively.

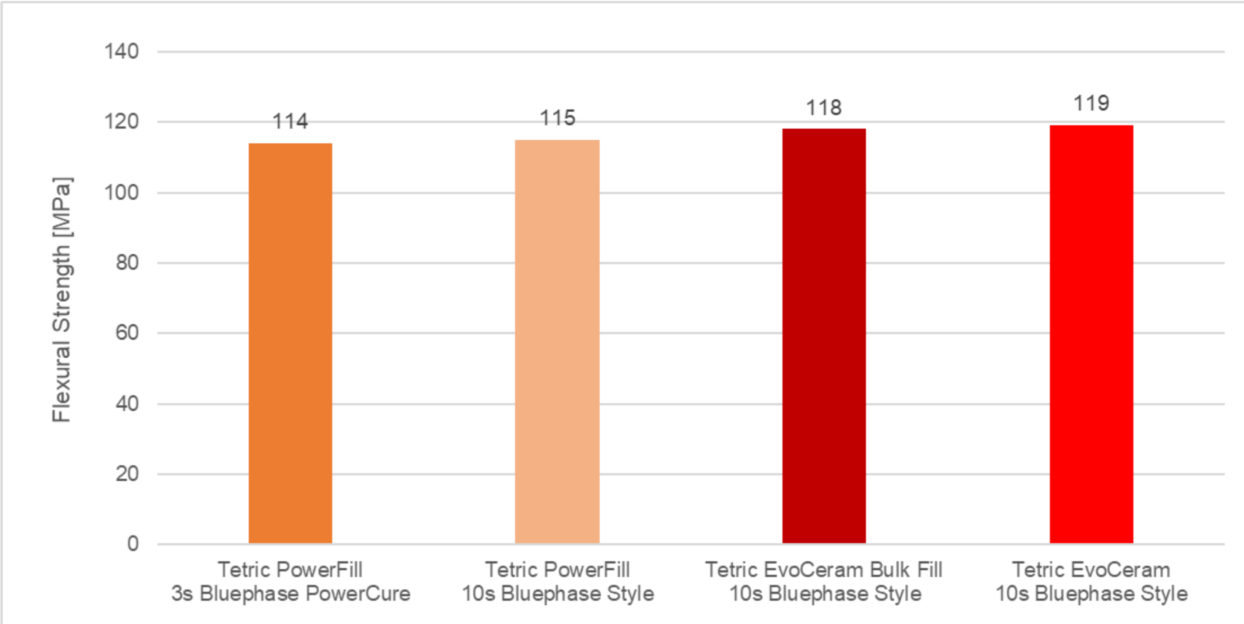


Fig. 55: Flexural strength of Tetric PowerFill and other sculptable composites with various curing protocols

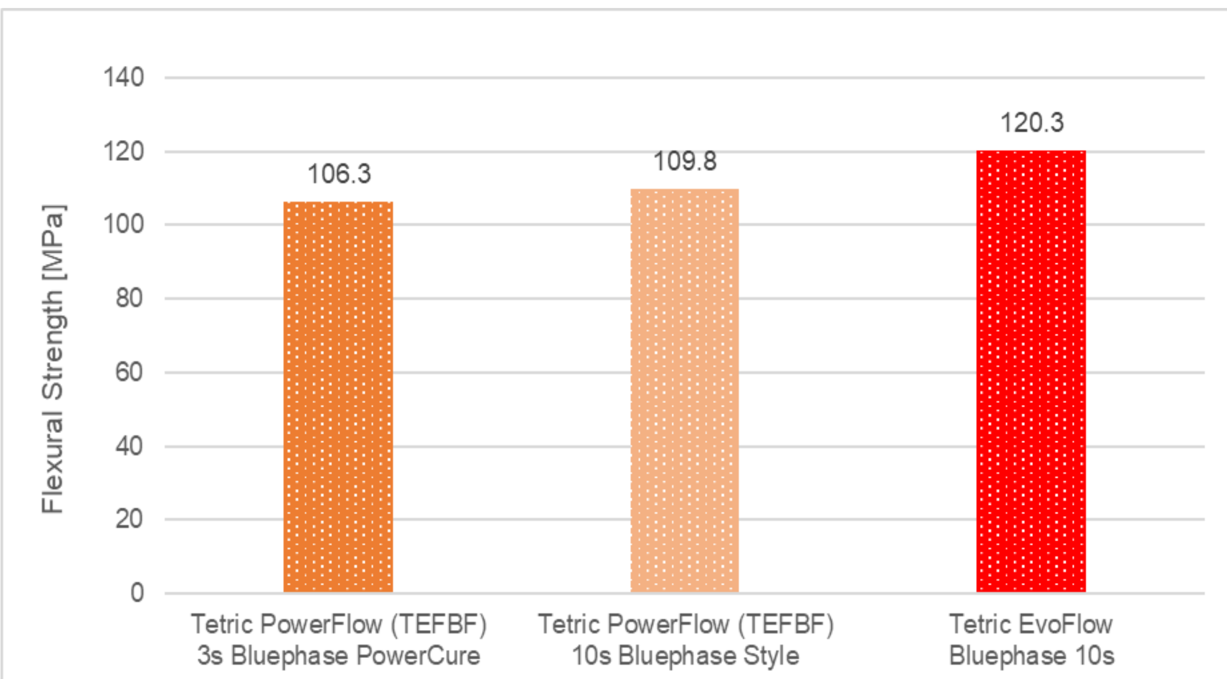


Fig. 56: Flexural strength of Tetric PowerFlow (TEFBF) and Tetric EvoFlow with various curing protocols

There was very little difference between the different sculptable composites (see figure 55) and flowable composites (see figure 56).

Characteristics of composite and curing unit: Flexural strength [31]

N. Ilie, University of Munich, Germany (2018)

Nicoleta Ilie also investigated the flexural strength of the same 3 groups of cured composites (n=20) outlined on page 49. Specimens of Tetric EvoCeram Bulk Fill and Tetric PowerFill (2mm x 2mm x 18mm) were prepared and subjected to three point bend testing for flexural strength and flexural modulus at a crosshead speed of 0.5mm/min. Specimens were stored at 37°C in distilled water for 24 hours prior to testing.

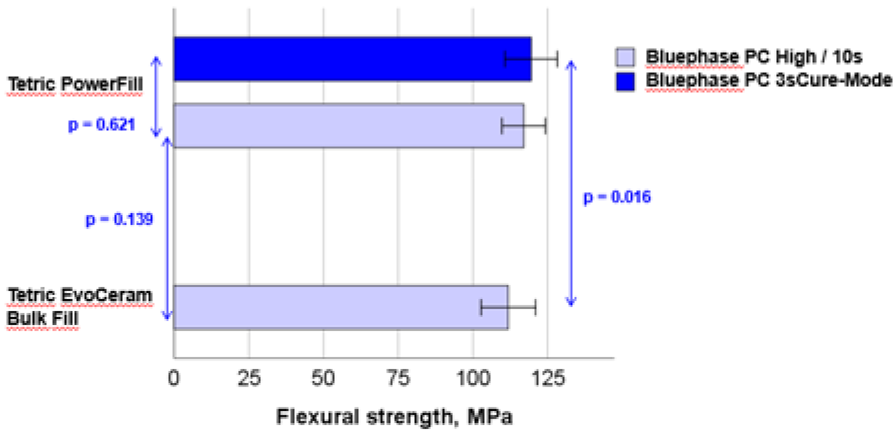


Fig. 57: Flexural strength of Tetric PowerFill under different curing protocols compared to Tetric EvoCeram Bulk Fill. N. Ilie, University of Munich, Germany

All flexural strength values in all groups were well beyond 80MPa. There was no significant difference in the curing mode used for the flexural strength values in Tetric PowerFill, or between Tetric PowerFill and Tetric EvoCeram Bulk Fill when cured in High mode for 10 seconds. There was however a significant difference between Tetric PowerFill and Tetric EvoCeram Bulk Fill when the former was cured for 3 seconds and the latter for 10 seconds (p=0.016) – however values were sufficiently high in both groups.

Flexural Modulus

The flexural modulus indicated no significant differences between either composite or curing group.[31]

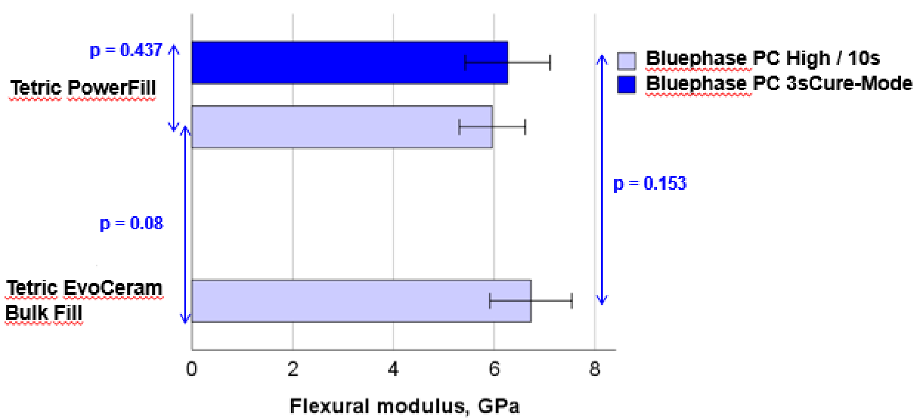


Fig. 58: Flexural modulus of Tetric PowerFill under different curing protocols compared to Tetric EvoCeram Bulk Fill. N. Ilie, University of Munich, Germany

5.2.5 Wear

The wear and polishability properties of Tetric PowerFill were investigated. Tetric PowerFlow was not evaluated in this respect as it is not exposed to wear nor is it polished. It is only indicated as a layer underneath a suitable sculptable composite such as Tetric PowerFill. Ivoclar Vivadent uses a Willytec chewing simulator to measure the wear resistance of restorative materials. The aim is to emulate mastication processes using a standardized procedure in order to obtain results that can be compared. To achieve this, standardized 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.

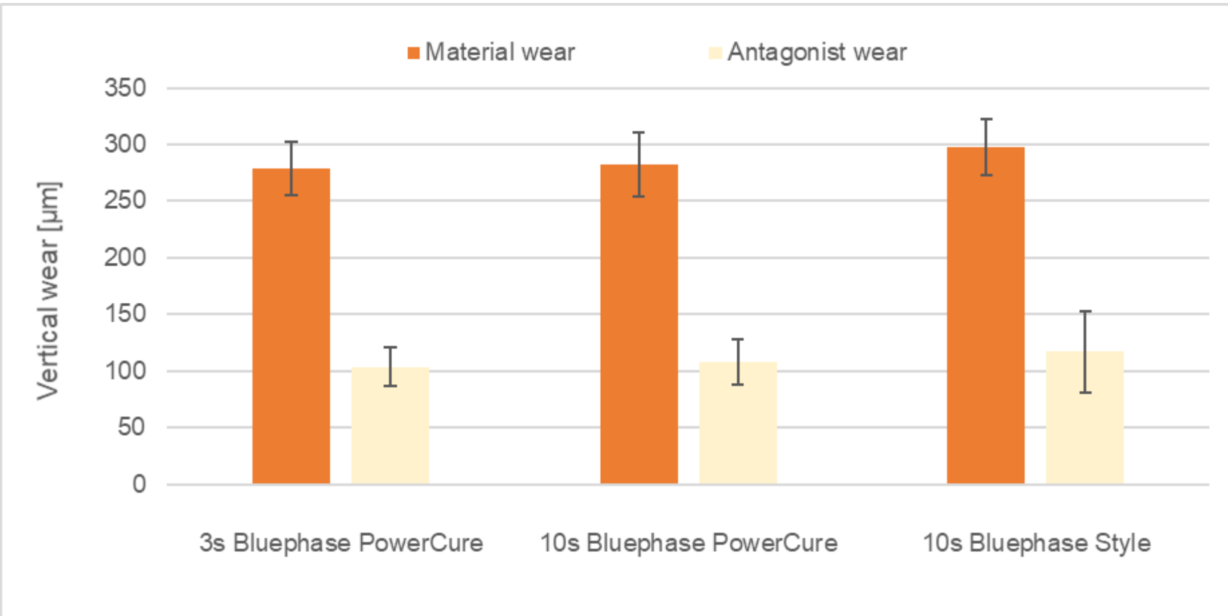


Fig. 59: Mean vertical wear of Tetric PowerFill and antagonist after different curing protocols (Preclinic, R&D Ivoclar Vivadent April 2014)

Tetric PowerFill exhibits medium wear of < 300 µm of vertical substance loss. There was no statistically significant difference between the different curing protocols in terms of wear.

5.2.6 Polishability

Polishing represents a critical step in direct restorative treatment. A pleasing surface gloss is decisive for the esthetic appearance whilst rough surfaces are conducive to staining and plaque accretion. The same curing groups as described above were investigated (n=8 per group). Tetric PowerFill 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 2N at 10,000 rpm under water cooling. Specimens were polished for 30 seconds in total, with the surface gloss and roughness measured at intervals of 10 s. The reference material was black glass with a gloss index value of 92.6. 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 suggests poor polishability.

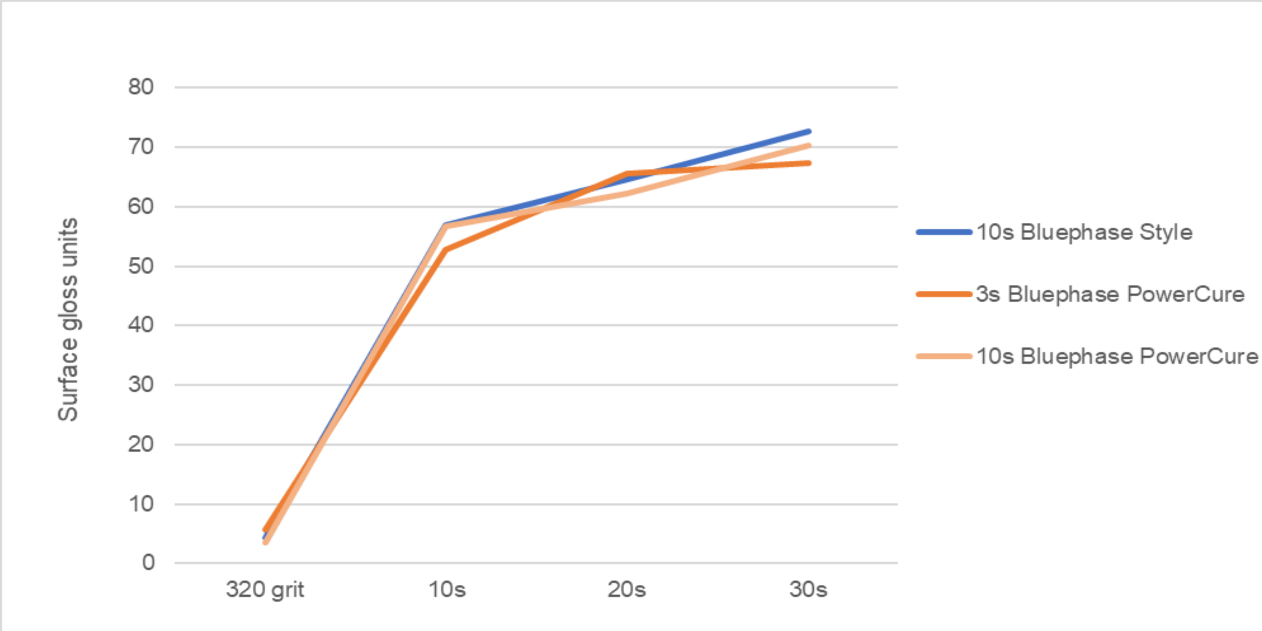


Fig. 60: Mean surface gloss of Tetric PowerFill after various curing protocols and polishing with OptraPol Next Generation for up to 30 seconds (Preclinic R&D Ivoclar Vivadent, Schaan, March, 2017)

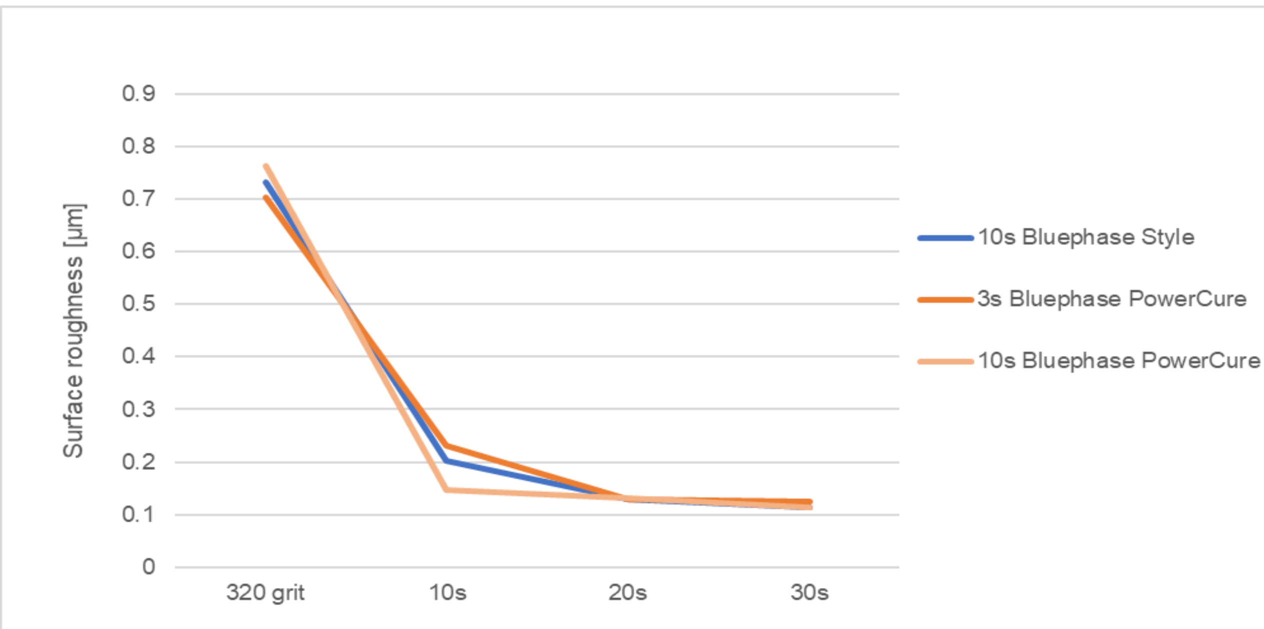


Fig. 61: Mean surface roughness of Tetric PowerFill after various curing protocols and polishing with OptraPol Next Generation for up to 30 seconds. (R&D Ivoclar Vivadent, Schaan, March 2017)

The polishability of Tetric PowerFill can be rated "good" with an average gloss value of around 70 and an average surface roughness of less than 0.2µm.

6. Investigations with Bluephase PowerCure

6.1 Light intensity / Irradiance evaluation

Ilie (Munich, Germany) and Price (Halifax, Canada) investigated and checked the functioning of various characteristics of the Bluephase PowerCure curing light.

Lamp characteristics and light absorption [33]

R. Price, Dalhousie University, Halifax, Canada (2018)

The Bluephase PowerCure has four different irradiance or light intensity programs depending on the clinical situation. The light is expressed as a function of the surface area of the light tip as discussed in section 2.4.3. Richard Price of the Dalhousie University in Halifax Canada – tested the irradiance of the Bluephase Power Cure (n=5) with an integrating sphere, when used in High, Turbo and 3s PowerCure-Mode. The irradiance calculations were made using an effective diameter of 9.25mm.

Bluephase PowerCure Program	**High**	**Turbo**	**3s PowerCure**
Manufacturer irradiance value (mW/cm^2)	1200 ±10%	2100 ±10%	3050 ±10%
Manufacturer irradiance range (mW/cm^2)	1080 - 1320	1890 - 2310	2745 - 3355
Power measured (mW)	774	1288	1954
Light intensity/irradiance measured (mW/cm^2)	1151	1917	2908

Table 7: Manufacturer quoted light intensity values as compared to values measured with integrating sphere *R. Price, Dalhousie University, Halifax, Canada* [33]

As previously noted, many light curing units do not deliver the intensity stated by the manufacturer. The light intensity/irradiance values measured for each Bluephase PowerCure program however fall exactly within the stated manufacturer ranges, e.g. 2908 mW/cm^2 measured in the 3s PowerCure-Mode, lies within the 3050 ±10% range of 2745 – 3355 mW/cm^2.

6.2 Polywave distribution

The wavelength pattern was also measured and is illustrated below showing the double peak polywave distribution against spectral radiant power in mW/nm. It can be seen that the power increases when a higher light curing mode is chosen (higher peaks around 450 nm wavelength), however this is only true for the light falling within the visible blue wavelength range. The spectral radiant power within the ultra violet range (peak ca. 412 nm) does not alter with the higher intensity modes.

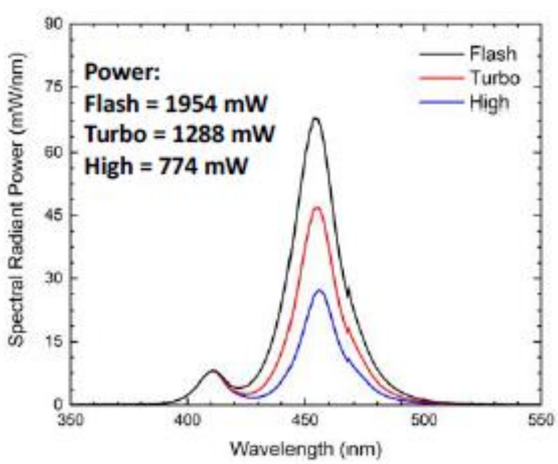


Fig. 62: Wavelength distribution of Bluephase PowerCure in various modes

6.3 Effect of curing distance

The effect of distance from the object to be cured (see section 2.4) was also investigated for each curing mode using an integrating sphere with an aperture of 8mm diameter. The irradiance measured of course decreases with increasing distance for all programs. The fall is however somewhat steeper for the 3s PowerCure-Mode.

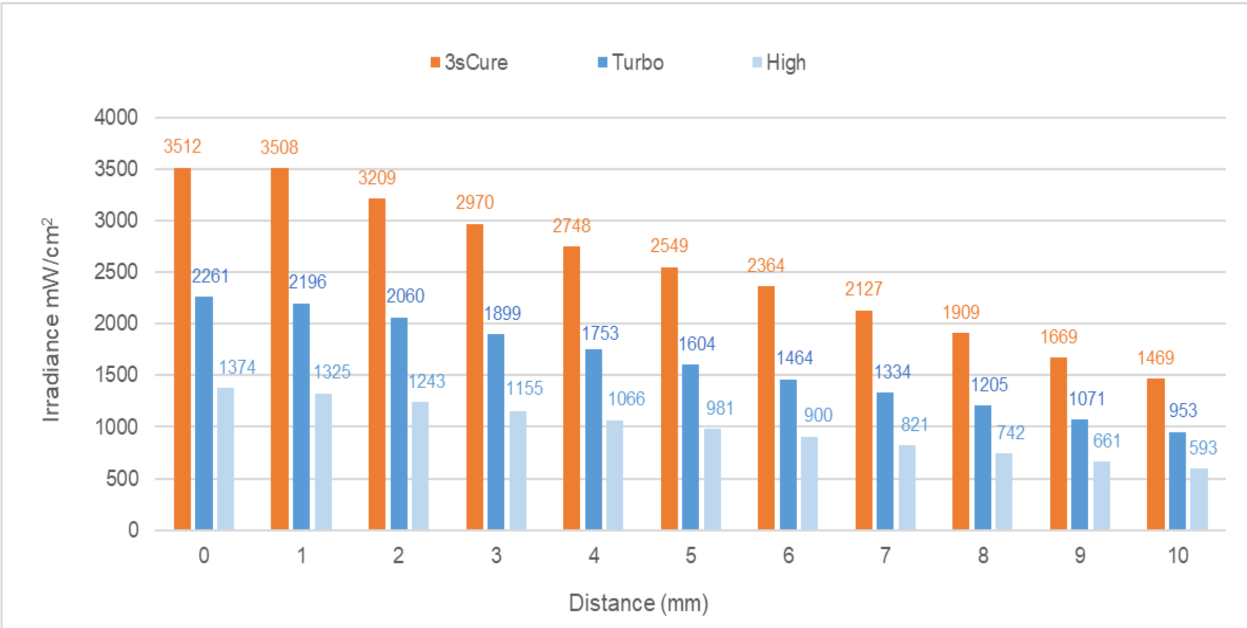


Fig 63: Effect of distance on irradiance shown for 3 programs of Bluephase PowerCure. *R. Price, Dalhousie University, Halifax, Canada*

6.4 Effect of light guide angulation

The Bluephase PowerCure in 3s PowerCure-Mode is only indicated for use when curing from the occlusal aspect is possible. This means the light guide should be placed with as little angulation as possible from the surface of the Class I or II restoration.

Characteristics of composite and curing unit: Flexural strength [31]

N. Ilie, University of Munich, Germany

Nicoleta Ilie from the University of Munich investigated the effect of angulation on the irradiance measured.

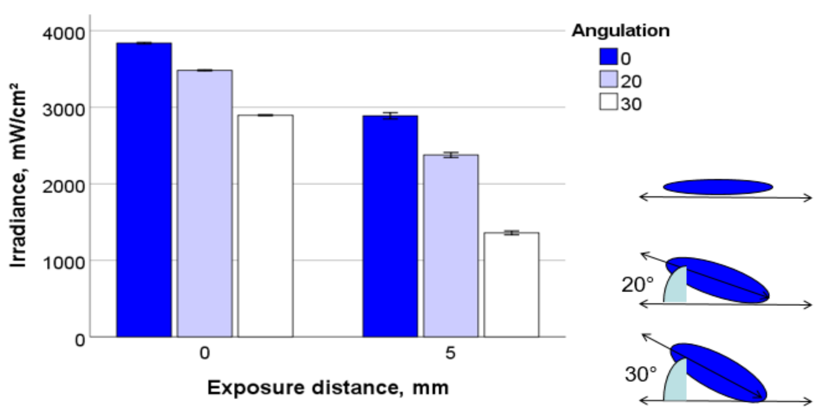


Fig 64: Effect of distance and light guide angulation on resultant irradiance with Bluephase Power Cure in 3s PowerCure-Mode. *N. Ilie, University of Munich, Germany*

The greater the angulation of the light guide, the lower the irradiance. This effect is even more pronounced the further away from the material the light guide is (5mm vs = 0mm). This illustrates the importance of the correct placement of the light guide. In cases where this is not possible, a longer curing time with a conventional curing mode should be employed in order to ensure adequate depth of cure.

The Polyvision feature provides assistance in situations e.g. where angulation suddenly increases due to hand-slippage. The user is alerted to improper use by a vibrating effect and the curing time is automatically extended by 10% if necessary.

7. Clinical experience with the 3s PowerCure-System

Heat development in the pulp and surrounding tissues (*in vivo/in vitro*)

Modern LEDs generate high light intensities. As a general rule, the higher the light intensity/irradiance of the curing light, the higher the release of energy and generation of heat. Heat is released during the polymerization process due to the exothermic reaction of the resin composite and the irradiation energy of the curing light. Effective resin polymerization though paramount, must not occur at the expense of the pulp or soft tissues adjacent to the tooth being cured. To prevent possible damage to the pulp or mucous membranes, curing lights must always be used according to the instructions for use and with clinical common sense and knowledge.

The dominant view, is that the temperature of the pulp should not increase by more than 5.5°C. It is largely expected that this limit avoids irreversible damage to the pulp. [34] This is based on a study carried out by Zach and Cohen (1965) [35] in monkeys. Increases in pulp temperature of between 4 °F (2.2°C) and 30 °F (16.7°C) *in vivo* were carried out whereby it was found that below a temperature change of 10°F (5.5°C) the stroma remained largely normal and pulp specimens were histologically unidentifiable from untreated controls. Beyond 10°F (5.5°C) changes were apparent though most were reversible.[35]

Bluephase PowerCure emits an irradiance of 3050 mW/cm^2 (± 10%). This generates perceptible warmth, which can be felt when the light beam is simply directed at the skin. Although tests carried out with Bluephase Power Cure do not indicate pulpal temperature changes beyond 5-5°C, for safety reasons deep cavities are contraindicated when using the 3s PowerCure-Mode. This mode is only indicated for Class I or II direct restorations that can be cured unhindered from the occlusal aspect.

To get a sense of the heat activity occurring in the pulpal chamber in a clinical situation an *in vivo/in vitro* study was set up with orthodontic patients requiring tooth extraction.

7.1 Analysis of pulp temperature and inflammatory response to radiant exposure from an experimental polywave LED light curing unit [36, 60]

Dr Cesar Arrais, State University of Ponta Grossa, Paraná, Brazil (2018/2019)

Objective: To investigate and compare *in vivo* pulpal temperature-increases during light exposure and *in vitro* histological and immunohistochemical changes to the pulp, in teeth scheduled for extraction when irradiated with either Bluephase 20i or Bluephase PowerCure.

Method: Consenting patients requiring the extraction of the first upper and lower premolars, for the purposes of orthodontic realignment, were recruited for the study. Patient-age ranged from 12 to 30 years. Both pulpal temperature (with 13 teeth per group) and histological evaluations (with 3 teeth per group) were carried out using different teeth. The pulpal temperature measurements were carried out *in vivo* before extraction. The histological investigations involved irradiation *in vivo*, followed by extraction and examination *in vitro*. Patients received local anesthetic injections prior to the investigation.

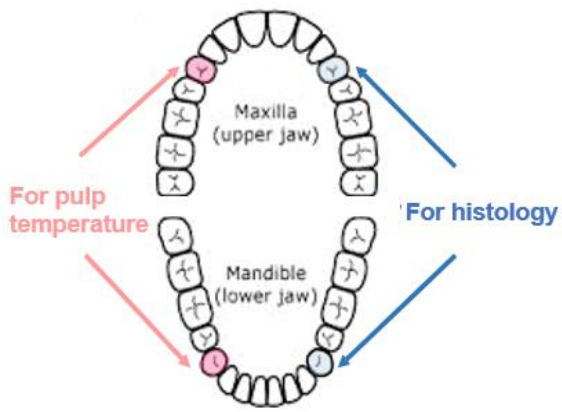


Fig. 65: Schematic representation of study tooth positionings

Pulp temperature change

The occlusal surface of each premolar was prepared using a round diamond bur followed by a small pencil-shaped bur to create an area of minute pulp exposure (figure 66a). A sterile thermocouple probe was inserted into the pulp chamber and sealed in place using a temporary restorative material (figure 66b), to minimize heat loss from the tooth.

Fig.66a: Occlusal cavity with minute pulp exposure

Fig. 66b: Sealed occlusal cavity with thermocouple

Fig. 66c: Buccal Class V preparation for light curing

A separate Class V cavity (figure 66c) near the gingival margin of the buccal surfaces was also prepared with a round diamond bur under constant water-cooling. The preparations left approximately 1mm of dentin between the axial wall and the pulp chamber. The polymerization light was used through this empty cavity representing a beyond-worst-case scenario. The teeth were exposed to light from either the Bluephase PowerCure or the Bluephase 20i lights for the varying time-periods shown in the table below – creating four groups.

	Bluephase PowerCure 3s PowerCure-Mode (3050mW/cm²)		**Bluephase 20i High Mode (1200mW/cm²)**	
Irradiance measured	3596 mW/cm²		1244 mW/cm²	
Group	Group 1	Group 2	Group 3	Group 4
Exposure time (and interval)	1 x 3s	2 x 3s (1s interval)	1 x 10s	2 x 10s (1s interval)
Radiant exposure (Irradiance x s)	≈ **10.8** J/cm²	≈ **21.6** J/cm²	≈ **12.4** J/cm²	≈ **24.9** J/cm²

Table 8: Irradiance measured and radiant exposure of four experimental (pulpal temperature) groups with two light curing units

The irradiance from each light was also tested using a laboratory grade spectroradiometer and an integrating sphere. The radiant exposure is calculated via the multiplication of the calculated irradiance and the number of seconds cured. Groups 1 and 3 and groups 2 and 4 involved similar levels of radiant exposure for comparison. The peak pulp temperature and temperature change (from baseline) were calculated. After the experiment, the teeth were extracted, the probe was reinserted into the aperture and the individual teeth were X-rayed to confirm correct probe positioning during intra-pulpal temperature testing.

Histological/Immunohistochemical change

Separate premolars (n=3 per group) underwent exposure (through a Class V cavity) to the different lights as described in the pulp temperature section. A further 3 premolars with Class V cavities that were not irradiated served as a control group. All cavities were filled with a glass ionomer post preparation (control group) or irradiation.

Fig 67a: Class V cavity on buccal surface.

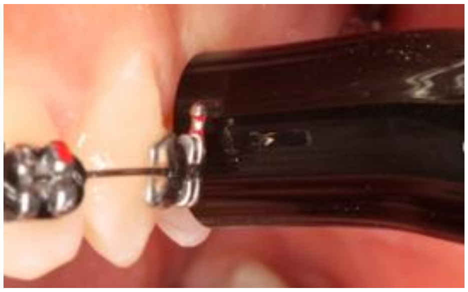


Fig. 67b: Light curing through cavity

After approximately 2 hours, the teeth were extracted (according to the patient's orthodontic plan) and fixed in 10% formalin, decalcified, embedded in paraffin, sectioned and stained with hematoxylin and eosin (H&E). A histological examination of the blood vessels and odontoblastic layer was carried out via optical microscope. Sections that were 3µm thick and adjacent to the H&E stained sections were used for immunohistochemical staining to determine the expression of the cytokine inflammatory mediators IL-1β and TNF-α. IL-1β is an important mediator of the inflammatory response and is involved in a variety of cellular activities, including cell proliferation, differentiation and apoptosis. TNF-α is involved in systemic inflammation and is a member of a group of compounds that specifically stimulate the acute phase of the inflammatory response.

Images were captured using a digital camera coupled to a stereomicroscope with 400x magnification and all analyses were based on visual aspects observed in the pulp tissue.

Temperature Results: The peak pulp temperature values and the temperature changes above baseline for each group are shown in the graphs below.

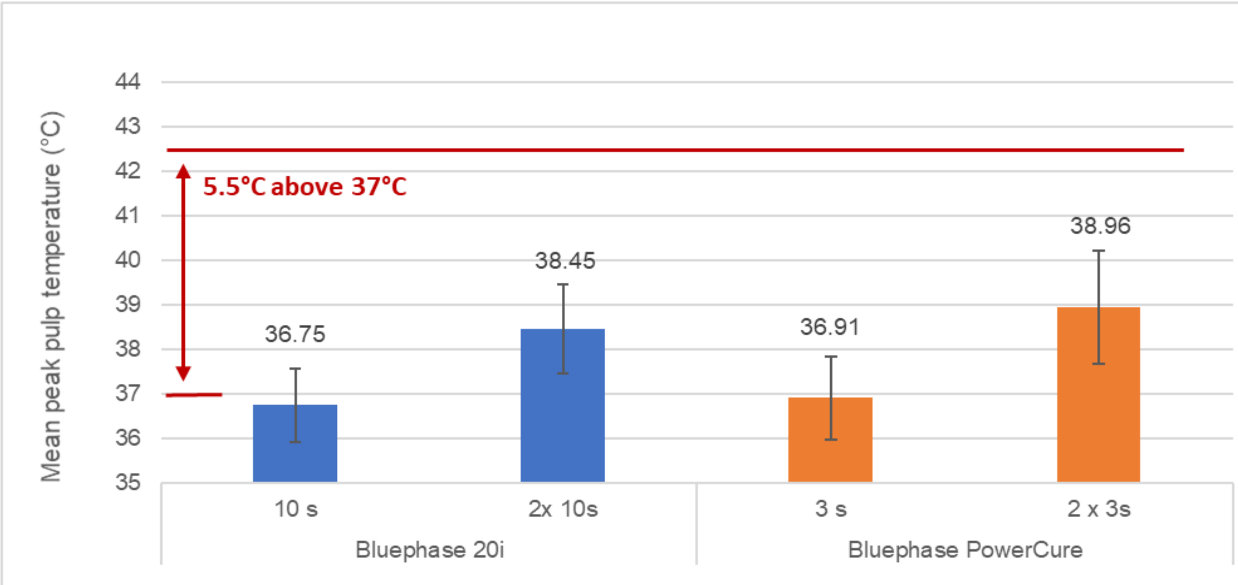


Fig 68: Peak pulp temperature values for teeth exposed to light for varying time-periods from Bluephase 20i and Bluephase PowerCure [36, 60]

The mean peak pulp temperature values are shown in the previous figure. There was no statistical difference in peak temperature between the Bluephase PowerCure 3s group (36.91°C) and the Bluephase 20i 10s group (36.75°C). The values were also very similar for the Bluephase PowerCure 6s exposure group (38.96°C) and the Bluephase 20i 20s exposure group (38.45°C). The radiant exposure for each group is shown in table 8. All values were also well below the accepted maximum temperature rise of 5.5°C in all four experimental groups i.e. below 42.5°C – considered the threshold peak temperature.

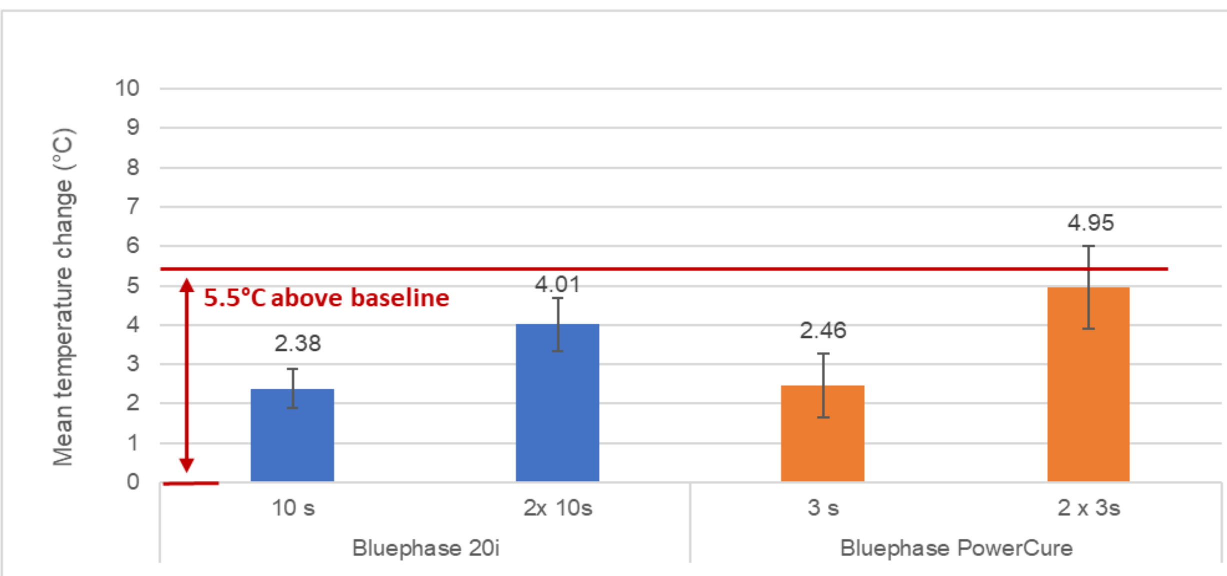


Fig. 69: Temperature change values above baseline temperature, for teeth exposed to light (for varying time-periods) from Bluephase 20i and Bluephase PowerCure

The previous graph illustrates the mean temperature change for each group – showing no statistical difference between the Bluephase PowerCure 3s group (2.46 °C) and the Bluephase 20i 10s group (2.38 °C). The baseline here was set at a physiological baseline level of 35.2°C (not 37°C) – based on experience from previous similar studies. All mean temperature change values were below the 5.5°C threshold. In three premolars however (see standard deviation) the temperature change in the Bluephase PowerCure (2 x 3s) exposure group did exceed the 5.5°C threshold when the baseline was set at 35.2°C however the peak temperature values in these three cases were all below 42°C.

Histological/Immunohistochemical Results: Histological analysis was performed to detect inflammatory signs and changes in pulp morphology regarding the odontoblastic layer and vascular changes such as dilation, engorgement, and permeability. The immunohistochemical analysis analyzed the presence of brown-colour spots as an indicator of the expression of the inflammatory mediators IL-1β and TNF-α. The results for test groups 1 and 3 are shown below.

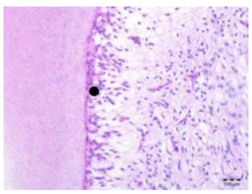
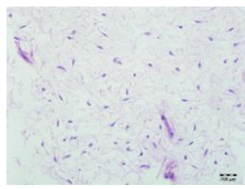
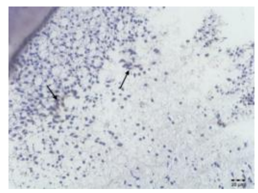
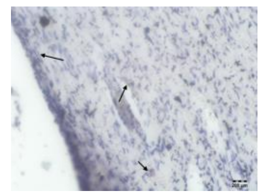
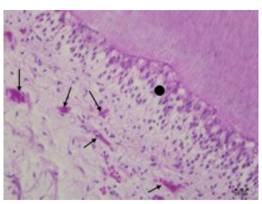
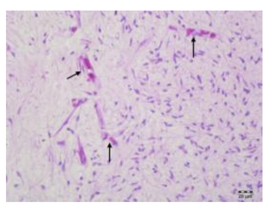
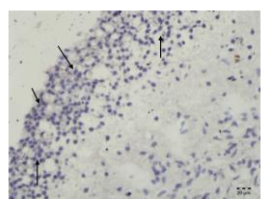
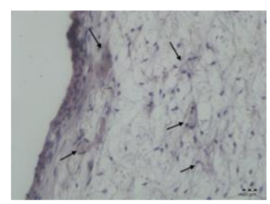
	Histological analysis		**Immunohistochemical analysis**	
			IL-1β	TNF-α
Bluephase 20i 10s				
Bluephase PowerCure 3s				

Table 9: Histological/immunohistochemical analyses of pulp after irradiation with different light curing units

In the histological analysis, the black circles indicated an intact odontoblastic layer after curing with either the Bluephase 20i or Bluephase PowerCure with no evidence of inflammatory cells in either group. Some lightly dilated and congested blood vessels were seen in the Bluephase PowerCure group. For the immunohistochemical analysis the black arrows show the light presence of both IL-1β and TNF-α after curing with both lights. The presence of cytokines in response to small heat stimuli is however to be expected and there has been no evidence of pulpal damage from the clinical use of Bluephase 20i. The histological and immunochemical results were also similar in the higher exposure groups 2 and 4.

Conclusion: All exposure modes resulted in lower peak pulp temperature and pulp temperature change than those considered harmful for the pulp (< 5.5°C). Histological changes and the presence of inflammatory mediators in pulp tissues following exposure to Bluephase PowerCure were similar to those observed with the established LED curing light Bluephase 20i. Within the limitations of this study tooth exposure to light emitted from the Bluephase PowerCure even in the worst case scenario (2x3s) is considered safe for the pulp.

7.2 Clinical investigation of 3s PowerCure-System for direct filling therapy: 6-month report [37]

Dr Lukas Enggist, Internal Clinic, F&E, Ivoclar Vivadent, Schaan, Liechtenstein (2018)

A one-arm prospective clinical trial was set up to investigate the 3s PowerCure-System, incorporating Adhese Universal, Tetric PowerFlow and Tetric PowerFill in Class I or II cavities of permanent molars or premolars.

Method

Between January and March 2018, 81 teeth were filled using the 3s PowerCure-System. In 6 cases it was discovered that the inclusion criteria had not been strictly adhered to e.g. a pulp capping would have been necessary - leaving 75 restorations. 25 patients received two fillings (n=50) and 25 patients received one filling (n=25). 50 molars and 25 premolars were treated. 12 fillings were Class I and the rest Class II. Three operators carried out the restorations. Two thirds of the group were men, representing a worst case scenario, as men exhibit higher chewing forces.

All restorations were carried out as follows: Adhese Universal was applied according to the Etch & Rinse technique. Tetric PowerFlow was applied in a layer of up to 4mm followed by a covering of Tetric PowerFill in one or two layers of at least 1mm. Each increment of each material was cured for 3 seconds using the PowerCure mode of the Bluephase PowerCure light (3050 mW/cm^2). Baseline evaluations were made 3-12 days after treatment. The 6-month recalls were carried out on average 177 days after baseline.

Results

49 of 50 patients could be evaluated after 6 months, as one patient (with 2 restorations) could not attend the recall. 73 restorations were therefore evaluated according to FDI-criteria.[61] The percentage of restorations rated clinically very good or good are shown in the diagram below.

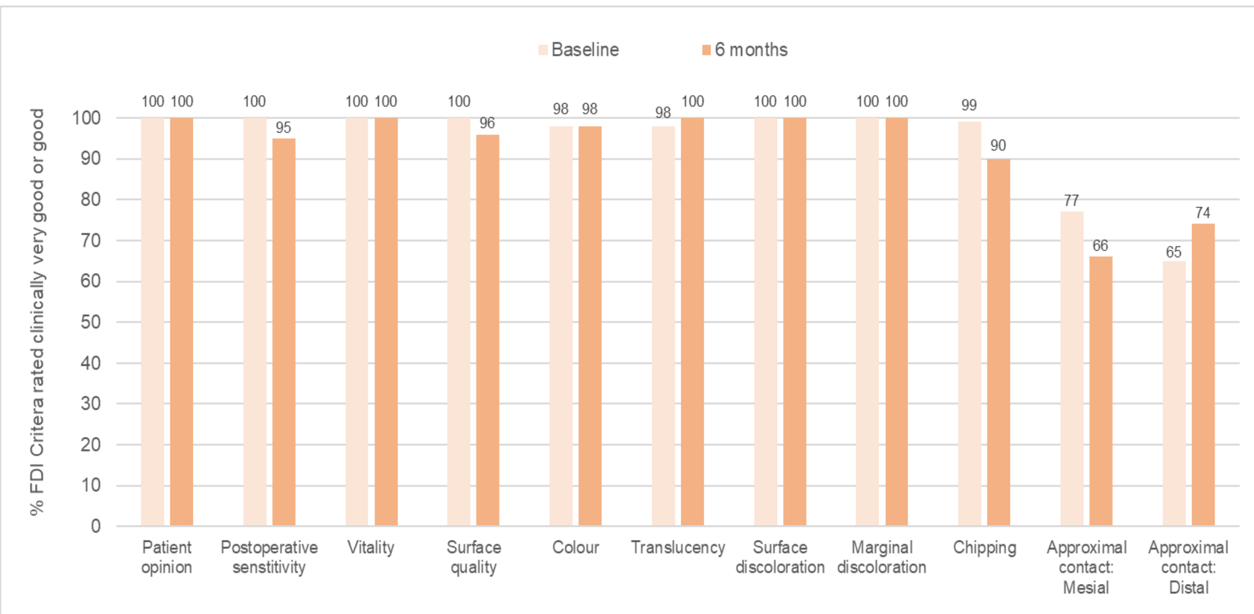


Fig. 70: Percentage of various FDI criteria graded as clinically very good (1) or clinically good (2) at baseline and after 6 months

Most criteria were rated clinically very good or good at baseline and after 6 months. All the teeth were vital and patient opinion was excellent.

Postoperative sensitivity was noted in 4 teeth (5%) either due to temperature or pressure. These were therefore rated as sufficient/3. The discomfort was mild in all cases as indicated via visual analogue scale (all values 3 or less on a 1-10 scale) but had lasted over one month.

Esthetics were rated highly, however in terms of surface quality 63% of the restorations were rated good rather than very good (33%), due to the somewhat matt nature of the surface or the presence of pores (which could be polished away).

Fig. 71a: Cavity preparation 25 MOD

Fig. 71b: 3s PowerCure restoration at 6-month recall

Seven restorations (10%) exhibited chipping, of which one constituted a fracture. These restorations were rated as sufficient (FDI 3) as they required minimal corrective action.

Over 50% of the contact points were optimal, however the approximal area exhibited a lower percentage of FDI 1 or 2 ratings than the other criteria - both at baseline and after 6 months. Distally 26% and mesially 34% were rated as sufficient. This seems to be due to the fact that with most of the fillings the contact point lay within the area of the flowable composite Tetric PowerFlow. Creating a contact point is somewhat more difficult with a flowable than a sculptable composite, as more pressure can be built up against the matrix with a sculptable material.

The margins of the restorations were also evaluated after 6 months in terms of marginal fracture, gaps and deficits. Here the percentage of the entire margin that was affected was estimated using SQUACE.100% of the restorations were rated FDI 1 or 2 for gaps or deficits and 99% (1 or 2) for marginal fracture.

Conclusion

Most criteria were rated clinically very good or good at baseline and after 6 months and all teeth remain vital. From a patient-standpoint, the 3s PowerCure method was unremarkable and similar to standard restorative therapy. Given that only 3 different colours of material were used, the fillings were notably esthetic. The differing translucencies of Tetric PowerFlow and Tetric PowerFill complimented each other well. After 6 months, all evaluations were rated sufficient (3) or higher and no fillings needed to be replaced or repaired. Four patients however experience ongoing if mild postoperative sensitivity.

7.3 Clinical Trial with 3s PowerCure-System – 6 month results [38]

Lawson N, Burgess J O. School of Dentistry, University of Alabama at Birmingham (UAB), USA (2018)

Objective: To measure the clinical outcomes of 4mm Tetric PowerFill restorations cured in 3 seconds with the Bluephase PowerCure curing unit over a 3 year period.

Method: Patients requiring at least one Class I or II restoration in vital teeth, were considered for inclusion. Rubber dam and anaesthesia were used for all restorations. Tetric PowerFill restorations in shades IVA, IVB and IVW were performed according to the instructions for use: Adhese Universal was applied according to the Total-Etch technique, cured in 3 seconds followed by up to 4mm increments of Tetric PowerFill, also cured occlusally in 3 seconds with the Bluephase PowerCure unit in 3s PowerCure-Mode (3050 mW/cm^2). In 3-surface restorations in molars (or restorations with palatal or buccal extension), two 3-second cures were applied for both the adhesive and the composite in cases where the light probe could not cover the entire mesial to distal distance.

42 patients were enrolled in the study, 3 were excluded due to screening failures: one patient could not open their mouth sufficiently, one had pre-operative sensitivity measured on the wrong tooth, and one moved out of state. The remaining 39 patients with an average age of 43 years, received between 1 and 3 restorations each - resulting in 69 restorations. Prior to the study, pre-operative sensitivity and vitality were assessed according to a 0-10 visual analogue scale (VAS) ranging from no pain to worst pain imaginable. Ten restorations were placed with a light cured resin modified calcium silicate base i.e. Theracal LC/Bisco - if the cavity was judged to be within 1mm of pulpal tissue. The base was cured for 10 seconds with a traditional curing light (1200 mW/cm^2). 51% of the restorations were performed on premolars and 49% on molars. 80% of the restorations were Class II, 20% Class I and most (80%) involved replacing old fillings. Some cavities required 2 bulk increments (54%) the remaining shallower cavities were filled with one increment of Tetric PowerFill.

The restorations were placed by four different clinicians but all evaluated by the same clinician/investigator, according to modified FDI-criteria[61] at baseline and after 6 months. Further evaluations will take place after 1, 2 and 3 years.

Results: 39 patients with 69 restorations were evaluated at baseline. 37 patients with 67 restorations could be reached and evaluated for the 6-month recall. The 2 drop-outs transpired, as one patient could not be contacted and another asked to withdraw from the study due to the inconvenience of the recall appointments. The following graph shows the percentage of restorations that were rated FDI 1: (clinically very good) or FDI 2: good (very good after correction) for various clinical characteristics at baseline and after 6 months.

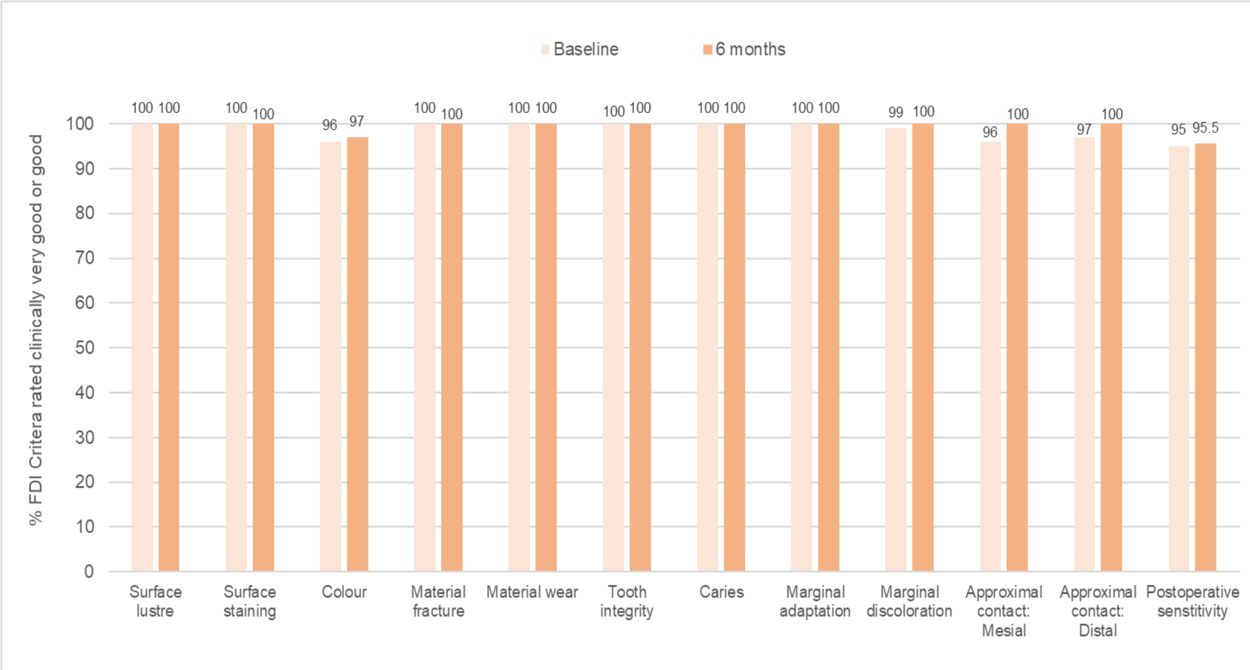


Fig. 72: Percentage of various FDI criteria graded as clinically very good (1) or clinically good (2) at baseline and after 6 months

Most restorations were rated FDI 1 across all the criteria with no percentage lower than 80% for FDI 1. For FDI 1 and FDI 2 evaluations together (see graph) the percentages were always above 95%. FDI 3 (clinically sufficient/satisfactory) was the lowest evaluation and was noted for post-operative sensitivity (4% and 4.5% at baseline and after 6 months respectively), for colour (4% and 3% at baseline and after 6 months respectively) and for marginal discoloration (1%), and mesial (4%) and distal (3%) approximal contacts - at baseline only. For colour at baseline 12% were also rated FDI 2 due to colour match issues with the IVA colour which was considered too translucent. It should also be noted that of the 100% achieving a FDI 1 + FDI 2 score after 6 months, 58% were rated FDI 2.

In terms of sensitivity, VAS values were recorded in response to cold, sweet, and various pressure stimuli pre-operatively and post-operatively. There was an overall reduction in perceived sensitivity at baseline, due to the fact that 71% of the restorations were performed due to either primary or secondary caries - thus most discomfort disappeared or was greatly reduced after restorative treatment. After six months this effect was maintained. Three patients experience remnant sensitivity.

The following photographs show the clinical appearance of two adjacent 3s PowerCure restorations both at baseline and after 6 months in two different patients:

Fig. 73 a-c: Example Case A: Clinical situation in two adjacent premolars at the preparation stage (left), at baseline (middle) and after 6 months (right)

Fig. 74 a-c: Example Case B: Clinical situation in two adjacent molars at the preparation stage (left), at baseline (middle) and after 6 months (right)

Conclusion: All the clinicians stated that the material polished well, had excellent handling properties and that the shortened light curing time was an improvement in the clinical workflow. In this investigation, the clinicians preferred the IVB shade. Minimal postoperative sensitivity was noted at baseline and some could be improved with occlusal adjustments. Most subsided within 1-4 weeks without intervention however, 6 restorations (in 3 patients) continued to exhibit manageable post-operative sensitivity for which intervention was not desired. The occurrence of FDI post-operative pain rated other than 1 (FDI 2 +FDI 3 = 9%) was within the range of similar studies carried out by the authors with different composite materials.

8. Summary: 3s PowerCure-System

Adhese Universal is a well-known, established universal adhesive and has been proven to work equally well as part of the 3s PowerCure-System, offering equivalent shear bond strengths to enamel and dentin and excellent marginal adaptation with Tetric PowerFill and Tetric PowerFlow.

Tetric PowerFill and Tetric PowerFlow provide a good degree of conversion at a 4mm depth and surpass the 80% top/bottom percentage threshold at this depth for all shades. They exhibit low shrinkage, excellent flexural strength and the sculptable Tetric PowerFill shows good polishability and esthetics when cured with the Bluephase PowerCure for 3 seconds. Tetric PowerFill and Tetric PowerFlow exhibit a similar clinical performance to Tetric EvoCeram Bulk Fill and Tetric EvoFlow Bulk Fill respectively and indeed to conventional composites.

External studies show that the Bluephase PowerCure unit delivers exactly what it promises in terms of irradiance and wavelength.

Preliminary clinical results show esthetic restorations with some minimal post-operative sensitivity and clinicians highly value the reduced polymerization times.

Efficient Esthetics

State of the art modern dentistry is an ongoing effort to simplify and improve clinical practice by creating ever more esthetic and durable materials that are easier and quicker to use. The 3s PowerCure-System reduces clinical time and technique sensitivity whilst maintaining expected levels of esthetics and quality.

9. Biocompatibility

Medical devices are subject to very strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 "Biological evaluation of medical devices" defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 "Evaluation of biocompatibility of medical devices used in dentistry". The biocompatibility of the 3s PowerCure products: Adhese Universal, Tetric PowerFill and Tetric PowerFlow was examined according to these standards.

9.1 Adhese Universal

Cytotoxicity

Cytotoxicity refers to the destructive action of a substance or mixture of substances on cells. The XTT assay is used to examine whether or not a substance causes cell death or inhibits cell proliferation in a cell culture. The XTT_{50} value refers to the concentration of a substance which reduces the cell number by half. The lower the XTT_{50} concentration of a substance, the more cytotoxic it is.

Uncured Adhese Universal was tested for cytotoxicity *in vitro* [39]. As expected (due to its monomer composition), uncured Adhese Universal exhibited a cytotoxic potential in the XTT assay with an XTT_{50} value of 138.1µg/ml. When the adhesive is polymerized, the cytotoxic compounds (monomers) react and are immobilized; i.e. the cytotoxic effect of the uncured adhesive is limited in time. To reduce the risk of any cytotoxic effect on the pulp in very deep cavities, areas close to the pulp must be selectively coated with calcium hydroxide liner (e.g. ApexCal); and subsequently covered with a pressure-resistant cement (e.g. a glass ionomer cement such as Vivaglass Liner). Most dental adhesives in clinical use exhibit a similar initial cytotoxic potential; however, negative effects have not been observed. When used according to the instructions for use, the risk for patients or users is negligible when compared to the overall benefit of the product.

Genotoxicity

Genotoxicity refers to the capability of a substance or a mixture of substances to damage genetic material. Adhese Universal has been examined regarding its potential gene changing properties via Ames mutagenicity tests[40]. Adhese Universal did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Adhese Universal is not considered genotoxic.

Sensitization and irritation

Like all resin-based dental materials, Adhese Universal contains methacrylate and acrylate derivatives. Such materials may have an irritating effect and may cause sensitization. This can lead to allergic contact dermatitis. Allergic reactions are extremely rare in patients, but are increasingly observed in dental personnel who handle uncured composite material on a daily basis.[41-47] These reactions can be minimized by clean working conditions and by avoiding contact of unpolymerized material with the skin. Commonly employed gloves made of latex or vinyl do not provide effective protection against sensitization to such compounds.

Conclusion

Adhese Universal is safe for use in humans if used according to the instructions for use. Uncured material is cytotoxic due to its monomer composition. After polymerization, monomers are immobilized within the polymer network thus the cytotoxic effect is minimized shortly after application. In its uncured state, Adhese Universal may cause sensitization to methacrylates, which is typical for all resin-based dental materials. According to the data available, Adhese Universal is not genotoxic.

9.2 Tetric PowerFill

Test samples of Tetric PowerFill that had been polymerized for 3 seconds using the Bluephase PowerCure 3s PowerCure-Mode (3050 mW/cm^2 +/-10%) were investigated.

Cytotoxicity
The above-mentioned samples were extracted for 24 ± 2 hours at 37 ± 1.0 °C in complete medium. Concentrations of the test item extract were tested in cytotoxicity assays *in vitro* (XTT test using the mouse cell line L929). Cytotoxic effects were not observed following incubation with the different test item extract concentrations up to the highest tested concentration (100%). Due to the lack of cytotoxicity, a XTT_{50} value could not be calculated. In conclusion, it can be stated that in this study and under the experimental conditions reported, the extract of the test item does not possess a cytotoxic potential. [48]

Genotoxicity
Mutagenicity testing is an accepted tool to evaluate the potential risk for genotoxicity of chemical substances and also medical devices. The most established mutagenicity test is the bacterial reverse mutation assay with strains of *Salmonella typhimurium* and *Escherichia coli* (Ames test).

The pre-cured samples of Tetric PowerFill and the chain transfer agent were tested. [49, 50] Neither extracts of Tetric PowerFill nor the chain transfer reagent induced gene mutations by base pair changes or frameshifts in the genome of the strains used. Therefore, the extracts of Tetric PowerFill [50] and the chain transfer reagent [49] are considered to be non-mutagenic.

Sensitization/Irritation
Like almost all dental composite materials Tetric PowerFill contains (di)methacrylates. Such materials may cause sensitization to methacrylates. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin [46, 47] The contact of uncured material with skin, mucous membrane or eyes should be avoided. As the undiluted extract of cured Tetric PowerFill does not possess a cytotoxic potential, it can be assumed that the risk of Tetric PowerFill causing irritation reactions is very low On the basis of cytotoxicity data and experience with similar products it can be concluded that according to the current knowledge Tetric PowerFill does not cause mucosal irritation when used according to the instructions for use.

Conclusion
On the basis of the toxicological evaluation of the products and the longstanding worldwide clinical use of similar materials such as Tetric EvoCeram Bulk Fill, it can be concluded that the benefits provided by the final product will exceed any potential risks produced by device materials. Except allergic reactions in rare cases, possible side effects are negligible compared to the clinical benefit for the patient.

9.3 Tetric Power Flow

Test samples of Tetric PowerFlow that had been polymerized for 3 seconds using the Bluephase PowerCure 3s PowerCure-Mode (3050 mW/cm^2 +/-10%) were investigated. The Tetric PowerFlow material is identical to that of Tetric EvoFlow Bulk Fill – only the potential polymerization mode (3s PowerCure) differs in the instructions for use.

Cytotoxicity
Extracts of samples were tested in cytotoxicity assays *in vitro* (XTT test using the mouse cell line L929). Also, the photoinitiator K69 (Ivocerin®) was tested in a cytotoxicity assay *in vitro*. For Tetric PowerFlow polymerized with the 3s PowerCure program the results were as follows:
Cytotoxic effects were not observed following incubation with the different concentrations of the extract of Tetric PowerFlow up to the highest tested concentration (i.e. 100% = undiluted extract). Due to the lack of cytotoxicity, a XTT_{50} value could not be calculated. In conclusion, it can be stated that in this study and under the experimental conditions in this study, the extract of the test item does not possess a cytotoxic potential [52]. The cytotoxic potential of Ivocerin (at various concentrations) was also determined with the XTT test by using the mouse cell line L929. Ivocerin did not possess any cytotoxic potential. [53]

Genotoxicity
Mutagenicity testing was carried out in the same way as for Tetric PowerFill using the reverse mutation test with strains of *Salmonella typhimurium* (Ames test). When cured in the standard fashion, the extracts of Tetric EvoFlow Bulk Fill (Tetric PowerFlow), did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Therefore, the extracts of Tetric PowerFlow are considered to be non-mutagenic in the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays. [54, 55]

When cured according to the 3s PowerCure program, Tetric PowerFlow extracts also did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Therefore, the extracts of Tetric PowerFlow are considered to be non-mutagenic in this *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay. [56]

Ivocerin was tested previously according to the Comet Assay [57], Ames test [58] and Miconucleus assay in bone marrow cells[59] and was found to be non-mutagenic.

Sensitization/Irritation
Like almost all dental composite materials Tetric PowerFlow contains (di)methacrylates, which may cause sensitization to methacrylates. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin.[46, 47] As the undiluted extract of cured Tetric PowerFlow does not possess a cytotoxic potential, it can be assumed that the risk of Tetric PowerFlow causing irritation reactions is very low.

Conclusion
On the basis of the toxicological evaluation of the product, the clinical experience already amassed with Tetric EvoFlow Bulk Fill and the longstanding worldwide clinical use of similar materials, it can be concluded that the benefits provided by the product will exceed any potential risks produced by device materials. Except allergic reactions in rare cases, possible side effects are negligible compared to the clinical benefit for the patient.

10. Literature

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