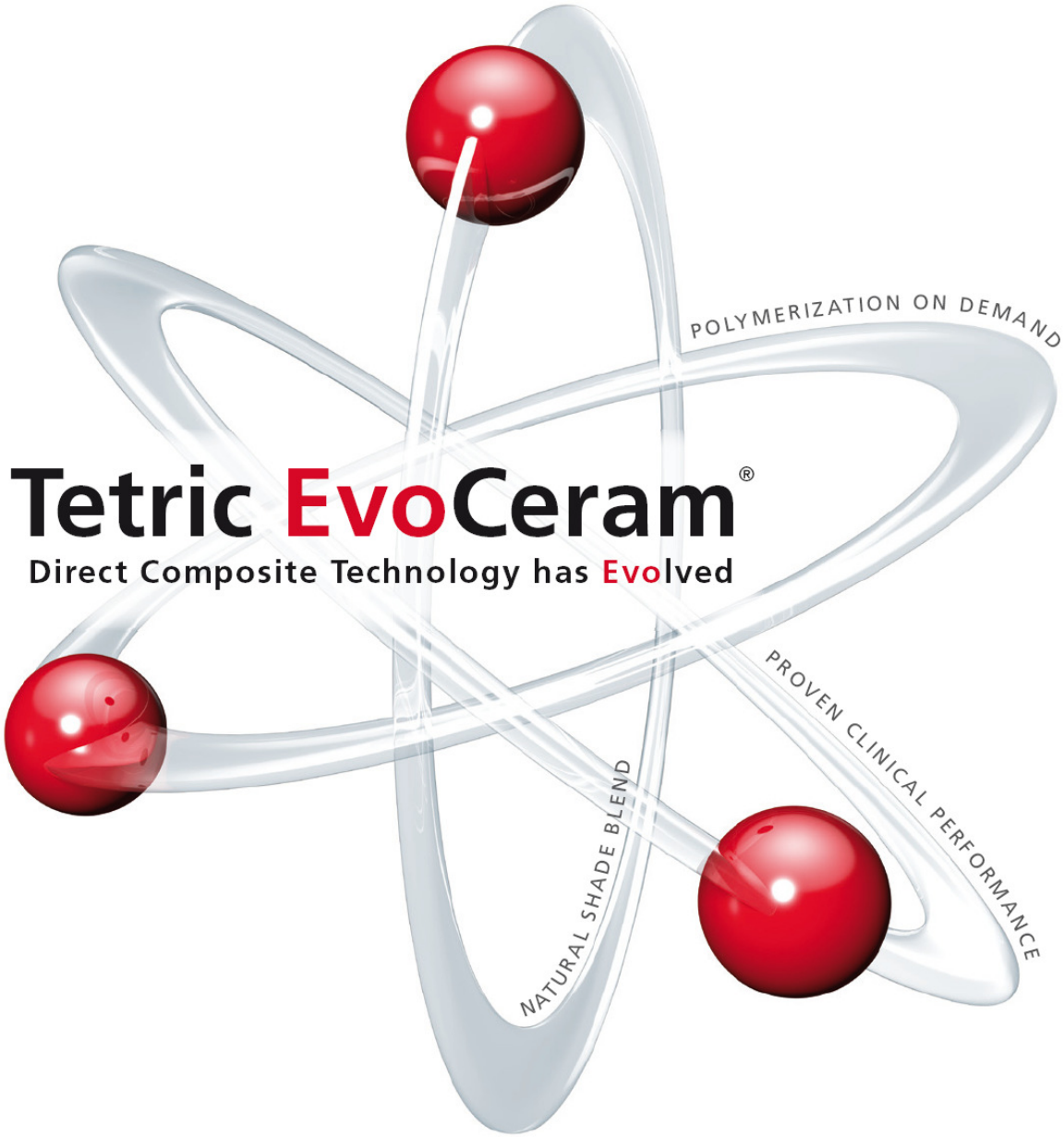


A sophisticated chemical composition offering a balanced combination of properties:

- **Proven clinical performance**
  Over 85,000,000 Tetric EvoCeram® restorations worldwide
- **Polymerization on demand (POD)**
  A long working time, combined with a short curing time
- **Natural shade blend**
  Coordinated light refraction indexes of fillers, monomer matrix and nano-colour pigments

Tetric EvoCeram®

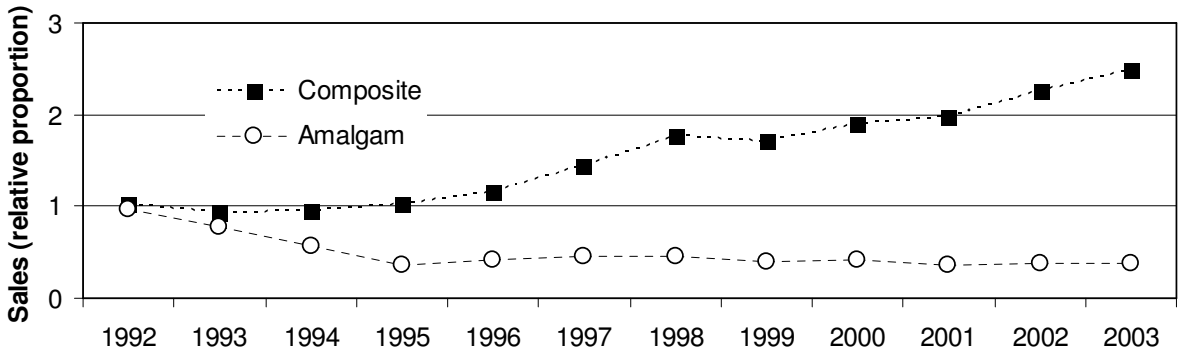
Scientific Documentation

ivoclar vivadent®
passion vision innovation

Table of contents

1. Introduction

Composite materials became available to dentistry in the sixties of the last century {Bowen, 1962 #6707}. First, they were mainly used in the anterior region, where the colour of Amalgam was not desired. After effective dentin bonding systems became available in about 1992, composites found broad use as universal filling materials. The growing demand for invisible restorations has led to an increase in the demand for composite materials and a corresponding decrease in the use of amalgam.



Sales of amalgam and composites in Germany. Source: GfK Healthcare, Nuremberg, Germany

The trend towards composites was accelerated in the nineties due to public concerns about health risks from amalgam fillings. The terms “amalgam replacement material” {Lutz, 2000 #3708;Setcos, 1995 #739} or “amalgam alternatives“ {Mjoer, 1997 #4177}, which initially were often used for composites, have sprung from this development. Today, the discussion: “amalgam or composites” is still ongoing. Nevertheless, it is becoming generally accepted that adhesive composite restorations are the first choice for direct restorations.

Of course, not only the desire of the patient for invisible restorations and the poor acceptance of amalgam have contributed to the success story of dental composites. This development also reflects a continuous development of dental restorative materials, which led to clinically reliable enamel/dentin adhesives and composite materials with the required physical properties, aesthetic possibilities and easy handling properties. In the following section, this *evolution* of composite materials is briefly outlined.

1.1 A short overview of the history of composites

1.1.1 Basics

The first step in the development of actual composite materials was made in 1962 with the synthesis of the new monomer Bis-GMA which was filled with milled quartz {Bowen, 1962 #6707}. At that time, only chemically curing two-component resin-based materials were available. In 1970, one of the first reports on a UV curable fissure sealant appeared {Buonocore, 1970 #7070}. UV curing was not a successful strategy because of the short penetration depth of UV light, limiting increment thickness and also due to health hazards linked to UV exposure. At the end of the seventies, the first reports on visible light curing dental filling materials were published {Bassiouny, 1978 #7069}. Only shortly later in 1980, Ivoclar Vivadent joined light curing with the microfilled composite Heliosit.

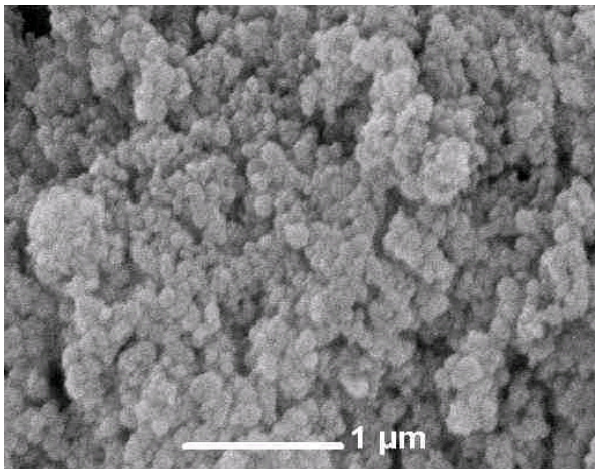
1.1.2 Filler technology

The first macrofilled composites were clinically not successful because of their inadequate surface properties and poor wear resistance {Lutz, 1983 #1265}. In 1974 a patent was granted to Ivoclar Vivadent on a composite employing microfillers {Michl, 1975 #7068}. Microfilled composites brought a breakthrough because they were the first material to be sufficiently wear resistant and maintained an acceptable surface quality during clinical service. However, it was clear that such microfillers could not overcome two problems. First, due to the high specific surface of microfillers, they strongly increased the viscosity of a composite, which does not allow for high inorganic filler contents. Therefore, microfilled composites exhibit a high polymerization shrinkage. Second, inorganic microfillers do not reinforce a composite material as well as macrofillers which results in low flexural strength and a low flexural modulus. These disadvantages, in particular the shrinkage, can largely be overcome by preparing a microfilled composite which is milled to a grain size that can be employed as filler in a dental material. Such fillers are called “prepolymers” or ”isofillers.” With IsoCap {Christensen, 1982 #6990;Wegelin, 1978 #6980} and Isosit {Mannerberg, 1977 #7071}, Ivoclar Vivadent materials were among the first to employ this technology. Heliomolar has so far been the most successful composite of this group.

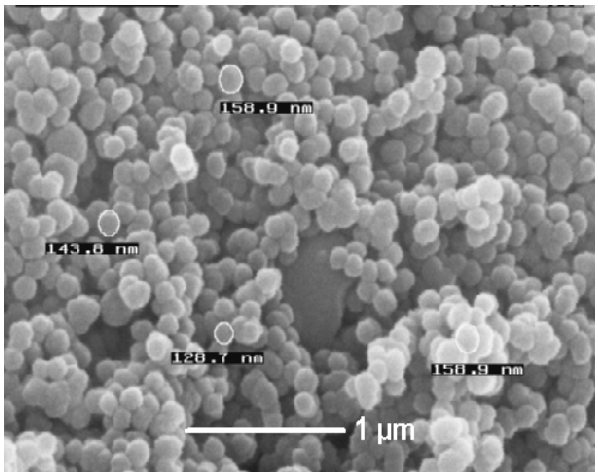
Hybrid composites represented a further step forwards with respect to the mechanical properties of composite materials. They contain of a coordinated mixture of inorganic microfillers and glass fillers with mean particle sizes of about 1 µm. This technology allows a very high filler loading, which results in higher physical strength and acceptable polymerization shrinkage. An example from the Ivoclar Vivadent range is Tetric, which was launched in 1992. With the introduction of Tetric Ceram in 1996, Ivoclar Vivadent provided the dental profession with a very user friendly and reliable hybrid composite, which became the market leader in Germany.

1.1.3 Filler size and composite wear

Microfilled composites typically exhibit a better wear resistance than hybrid composites. Indeed, it was found that smaller filler particles result in less wear {Suzuki, 1995 #100}. Previously, only spherical silicon dioxide fillers were available, which had homogeneous particle sizes in the micro- (< 1 µm) and nanofiller range (< 100 nm). Such silicon dioxide fillers were either produced in a pyrogenic or a sol-gel process, where particles grew to the desired size during the manufacturing process.

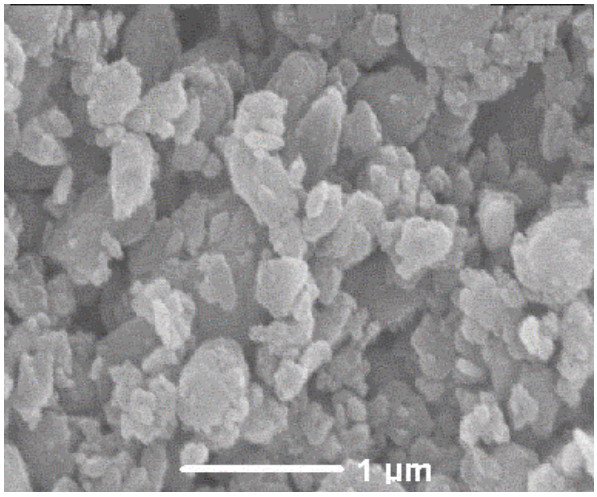


Silicon dioxide microfiller with a mean particle size of 40 nm.

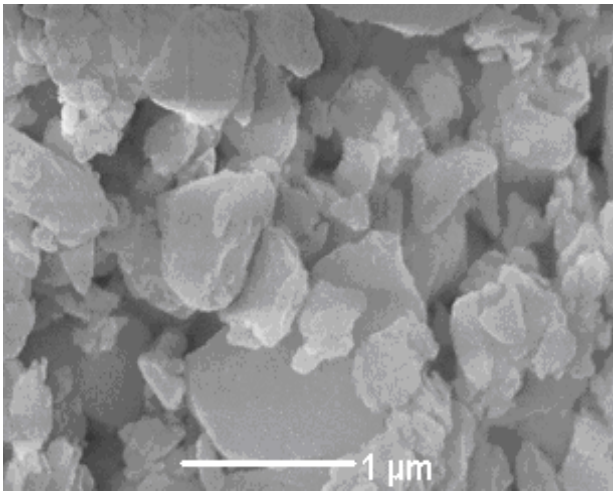


Mixed oxide filler with a particle size of a mean particle size of 160 nm

The glass fillers typically used in hybrid composites are made by means of a milling process. Only recent technical progress has allowed to obtain microfillers through milling (see picture below).



Barium aluminium silicate glass microfiller of a mean particle size of 0.4 µm



Barium aluminium silicate glass filler of a mean particle size of 0.7 µm

By using a glass microfiller with a mean particle size of 0.6 µm, the wear of Tetric EvoCeram could be dramatically improved compared to a composite employing a filler with a mean particle size of 1.0 µm.

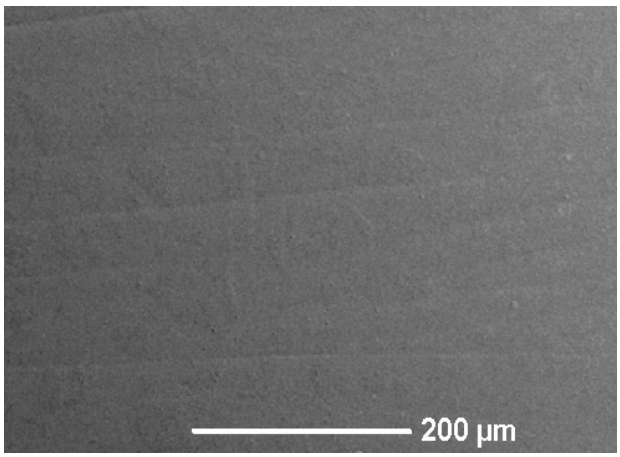
1.1.4 Polymerization shrinkage

Today, more than 40 years after dental composite materials were invented, they still employ the same chemistry for the monomer matrix. High molecular weight dimethacrylate components are cured by radical polymerization. Shrinkage has always been intrinsic to this type of polymerization. Since polymerization shrinkage may result in poor marginal quality due to the forces exerted on the adhesive layer, efforts have been made to reduce both, the volumetric shrinkage and the shrinkage stress occurring during polymerisation. In 2001 Ivoclar Vivadent launched InTen-S, which exhibits an exceptionally low polymerization shrinkage of only 1.6 % (v/v). In vitro tests on the marginal quality using various adhesives consistently resulted in better margins when InTen-S was employed compared to a composite with higher polymerization shrinkage.

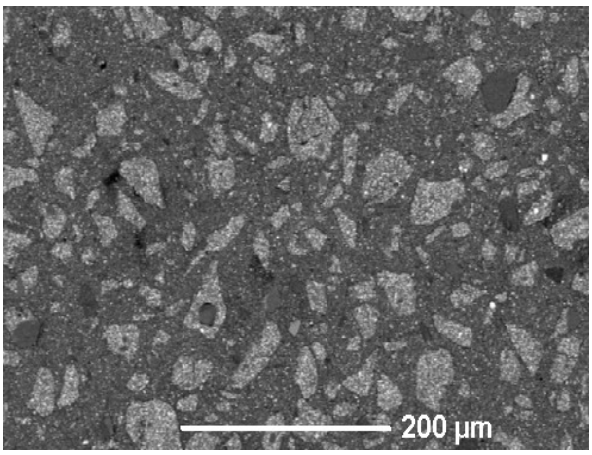
1.1.5 Isofillers – the key to combine the advantages of micro- and macrofillers

We have learned above that different types of fillers provide a composite material with specific properties. The use of microfillers results in a high wear resistance and good polish-ability. However, microfillers strongly increase the viscosity of composites which limits the proportion of the filler. This results in high polymerization shrinkage. In contrast, macrofillers allow for high physical strength and low polymerization shrinkage. However, they also result in poor wear resistance and a rough surface.

With isofillers the disadvantages of microfillers can be overcome. For this purpose, a microfilled composite is produced and milled until it has a grain size similar to that of a macrofiller. When such an isofiller is used to manufacture a composite, it is homogeneously integrated into the material during polymerization. Hence, a material having handling and physical properties comparable to a hybrid composite can be realized by only using inorganic microfillers. This is illustrated in the pictures below, which show the surface of a polished Tetric EvoCeram specimen in the scanning electron microscope. No surface irregularities are visible in the picture on the left. The isofillers only become visible in the material contrast mode.



SEM picture of a polished surface of Tetric EvoCeram. The smoothness is obvious.

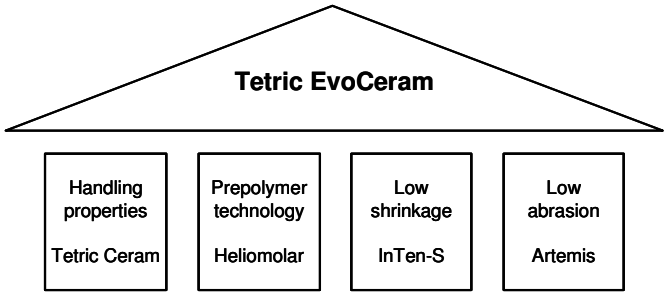


The same surface in the material contrast mode. The isofiller particles appear brighter because they contain the radiopaque filler ytterbium trifluoride.

1.2 Tetric EvoCeram - The Evolution of Composite Technology

The above introduction has shown that Ivoclar Vivadent has been at the leading edge of composite development. Many innovations in composite development, such as the isofiller and the radiopaque filler ytterbiumtrifluoride, have been brought to dentistry by Ivoclar Vivadent researchers. What at one time was an innovation is now proven technology. This competence in composites, which Ivoclar Vivadent has gained during recent decades, has resulted in the development of Tetric EvoCeram.

Tetric EvoCeram matches the exceptionally low polymerization shrinkage of InTen-S and exhibits considerably less in vitro wear than Tetric Ceram. These improvements have been achieved while the very favourable handling properties of Tetric Ceram have been maintained. Tetric EvoCeram also comprises features of nanotechnology. While the material contains only a small quantity of inorganic nanoparticles, “nano additives” have been incorporated in a targeted fashion. The rheological modifier contained in Tetric EvoCeram is an example of such a nano additive. As in Tetric Ceram, this modifier is responsible for the material’s viscosity and good pliability. Furthermore, organic pigments, which are covalently bonded to silicon dioxide particles in the nanoscale region, enable an outstanding color match of Tetric EvoCeram with natural tooth structure.



Hence, the knowledge gained with the isofiller technology of Heliomolar, the experience obtained with Tetric Ceram in adjusting the handling properties, the knowledge how to minimize polymerization shrinkage and wear are the pillars of Tetric EvoCeram. Tetric EvoCeram is not a revolutionary new development introducing technology to dentistry that has not yet been proven. Rather, it is the evolution of previous outstanding and reliable products.

1.3 Tetric EvoFlow – the ideal supplement to Tetric EvoCeram

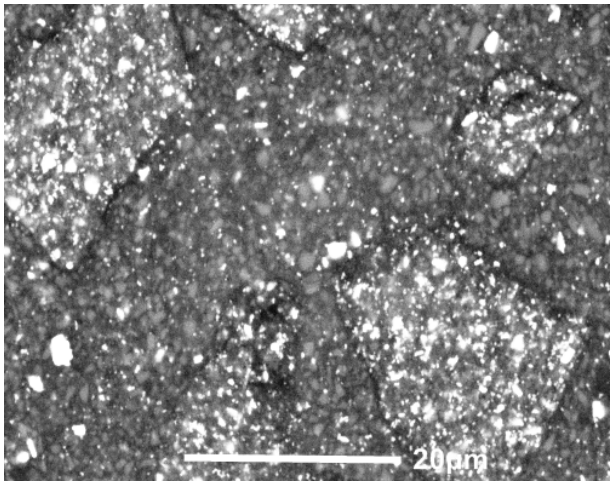
Flowable composites have been introduced to the market since 1995. In 1996, Ivoclar Vivadent launched Tetric Flow, a flowable version of Tetric Ceram. The product quickly established itself as the leader in this segment in many markets.

Flowable composites facilitate the restoration of cervical defects, micro-cavities and extended fissures. There were only less satisfactory or very time-consuming restoration possibilities for this indication in the past {Buddenberg, 1998 #2883}. In addition, flowable composites are suitable as an initial layer in large Class I and Class II cavities, as they more easily adapt to the cavity.

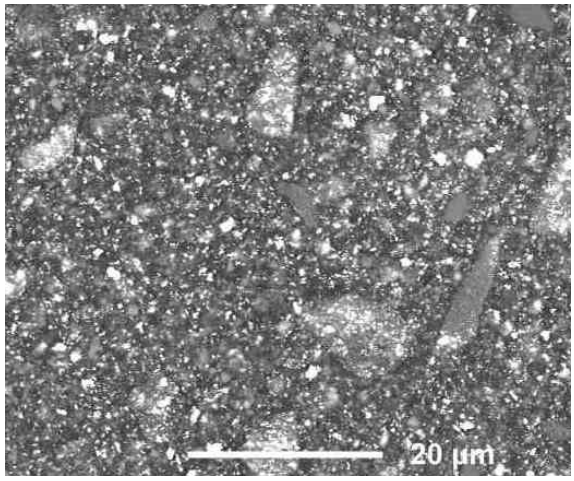
Since 2005, Tetric EvoCeram has successfully replaced Tetric Ceram. Now, Tetric EvoFlow is the successor of Tetric Flow and offers the following advantages:

- Ideal supplement to Tetric EvoCeram
- Vita shades, i.e. optimum coordination with Tetric EvoCeram shades
- Even higher radiopacity
- Excellent polishing properties
- Lower polymerization shrinkage
- Longer processing time
- Free of triethylene glycol dimethacrylate (TEGDMA)

As already employed in Tetric EvoCeram, prepolymers have been used in Tetric EvoFlow. However, these are finer ground than those used in Tetric EvoCeram (see Figure).



Surface of polished Tetric EvoCeram in the material contrast mode.



Surface of polished Tetric EvoFlow in the material contrast mode.

In order to be used as a light-curing cementation material, the material has to exhibit a film thickness of less than 50 µm according to ISO 4049. The use of these finely ground prepolymers allows a very low film thickness to be achieved. Therefore, Tetric EvoFlow, as already Tetric Flow, can be used as a light-curing luting material.

2. Technical Data

Tetric EvoCeram

Light-curing composite

Standard – Composition	**(in weight %)**
Bis-GMA, Urethane dimethacrylate, Ethoxylated Bis-EMA	16.8
Barium glass filler, Ytterbiumtrifluoride, Mixed oxide	48.5
Prepolymers	34.0
Additives	0.4
Catalysts and Stabilizers	0.3
Pigments	< 0.1

Physical properties

In accordance to ISO 4049 - Polymer-based filling, restorative and luting materials

Flexural strength	120	MPa
Flexural modulus	10000	MPa
Water absorption (7 days)	21.2	µg/mm³
Water solubility (7 days)	< 1.0	µg/mm^3
Radiopacity (all colours without Bleach)	400	% Al
Radiopacity (Bleach I)	200	% Al
Radiopacity (Bleach L, M, XL)	300	% Al
Depth of cure	> 1.5	mm
Compressive strength	250	MPa
Transparency (dependent upon opacity)	6.5 – 20.0	%
Vickers hardness HV 0.5/30	580	MPa
Density	2.10	g cm^{-3}

Tetric EvoFlow

Light-curing composite

Standard – Composition	**(in weight %)**
Bis-GMA, Urethane dimethacrylate, Decandioldimethacrylat	37.6
Barium glass filler, Ytterbiumtrifluoride, Mixed oxide, Highly dispered silica	41.1
Prepolymers	20.4
Additives, Catalysts and Stabilizers	0.9
Pigments	< 0.01

Physical properties

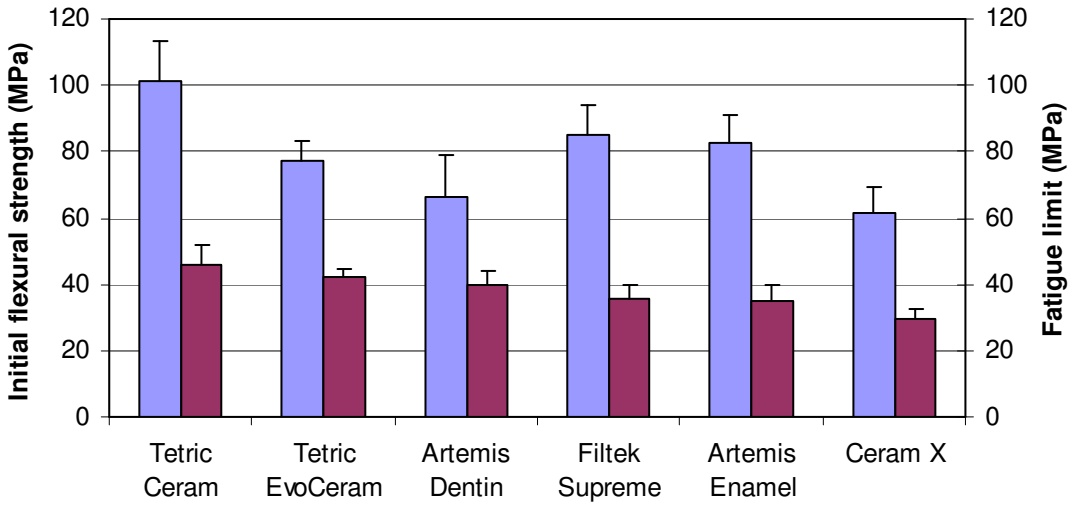
In accordance with ISO 4049 - Polymer-based filling, restorative and luting materials

Flexural strength	114	MPa
Flexural modulus	5100	MPa
Water absorption (7 days)	21.0	µg/mm³
Water solubility (7 days)	0.1	µg/mm³
Radiopacity (all colours without Bleach)	360	% Al
Radiopacity (Bleach I)	250	% Al
Radiopacity (Bleach L, M, XL)	280	% Al
Depth of cure	> 2.0	mm
Compressive strength	260	MPa
Vickers hardness HV 0.5/30	320	MPa
Transparency (dependent upon opacity)	6 - 30	%
Density	1.78	g/cm³

3. Laboratory investigations

3.1 Fatigue strength

The composite market has seen a race for high flexural strength values in recent years. In compliance with the relevant internationally standardized tests and other methods, the flexural strength of the test specimens is normally determined after 24 hours of water storage. These tests establish only initial strength values and do not take into account the fact that dental materials are exposed to changing levels of mechanical loading and moisture in the oral cavity for long periods. To do justice to these conditions, University Erlangen first stored the specimens in water at 37°C for 2 weeks before subjecting them to initial 4-point flexural strength testing. An additional number of specimens were subjected to fatigue strength testing. For this purpose, a staircase method was used to determine the force that can be applied 10,000 times to the specimens before they break. The value established in the process represents the fatigue limit.



Initial 4-point flexural strength after storage in water for 2 weeks (on the left) and fatigue limit (on the right) after 2 weeks of water storage and 10,000 cycles of mechanical loading.

Study: Dr. Ulrich Lohbauer, University Erlangen, Germany

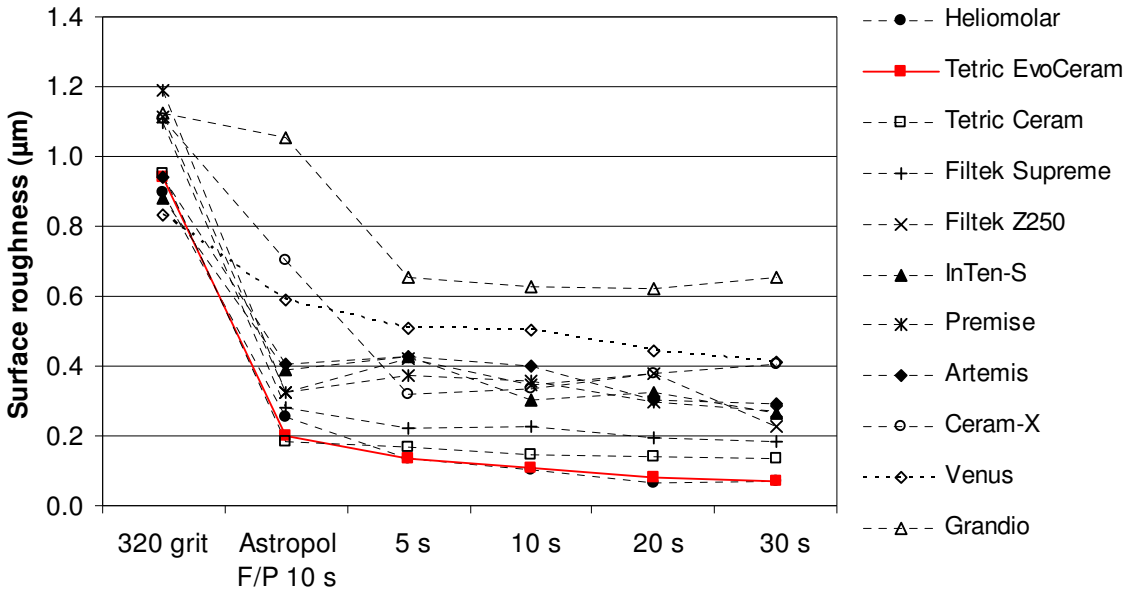
The results show that the fatigue strength values of Tetric EvoCeram are among the highest of all the materials tested after 2 weeks of storage and 10,000 cycles of mechanical loading. Compared to the other materials, Tetric EvoCeram showed a relatively small loss of strength in the course of mechanical loading.

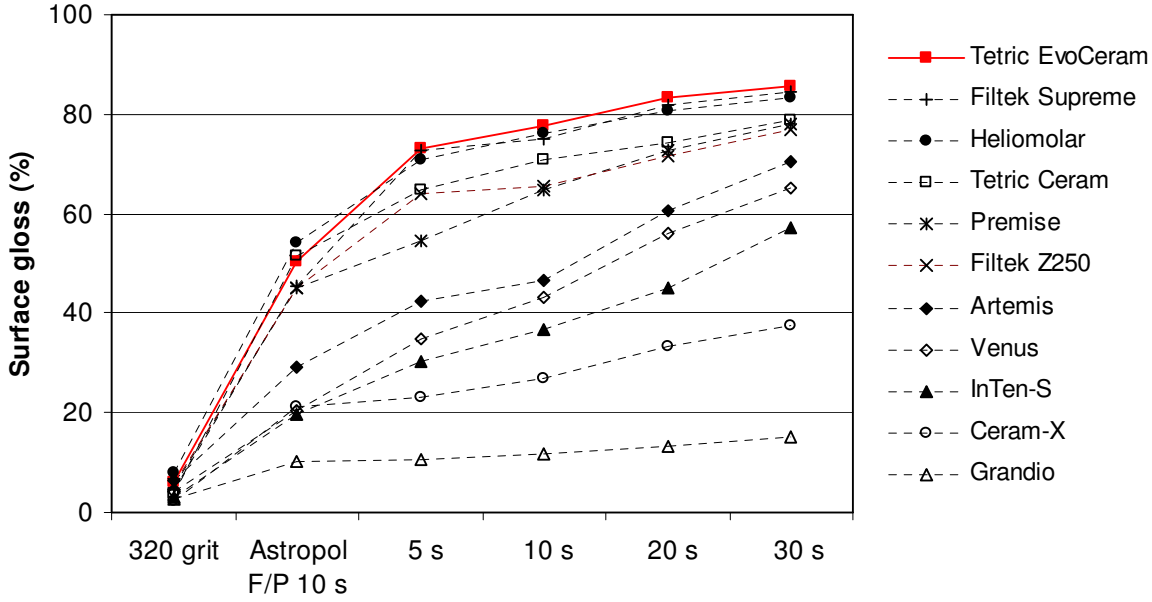
3.2 Surface roughness and gloss as function of polishing time

A good surface polish is crucial for the clinical performance and the aesthetic appearance of a composite restoration. A rough surface can lead to discoloration and plaque accumulation. This step is particularly critical, because it is the last to be performed during a direct filling therapy. Therefore, particular attention has been paid to develop a product with favourable polishing properties. Both the final surface polish achieved and the time needed to polish the restoration have been optimized.

Eight samples were prepared for each material according to the manufacturer's instructions. After dry storage at 37°C for 24 hours, the samples were roughened with 320 grit abrasive paper. This resulted in the initial sample roughness. The surface roughness R_a was measured with an FRT MicroProf measuring device. The surface gloss was determined with a Novo-Curve gloss meter.

Subsequently, the samples were prepolished with Astropol F and Astropol P discs for 10 s each at a standardized pressure of 2 N at 10,000 rpm under water cooling. The final polish was accomplished with the Astropol HP discs. The final polishing procedure was interrupted at intervals of 5 seconds to measure the surface roughness and gloss.

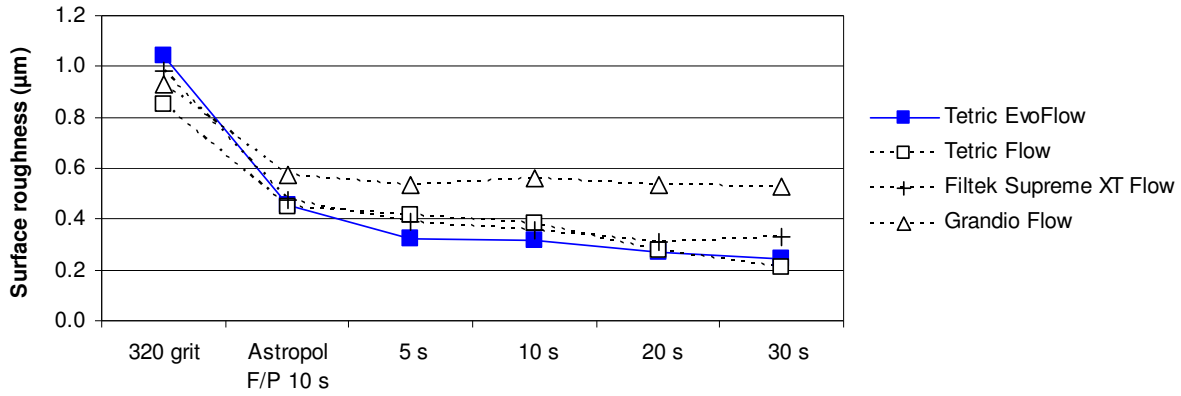


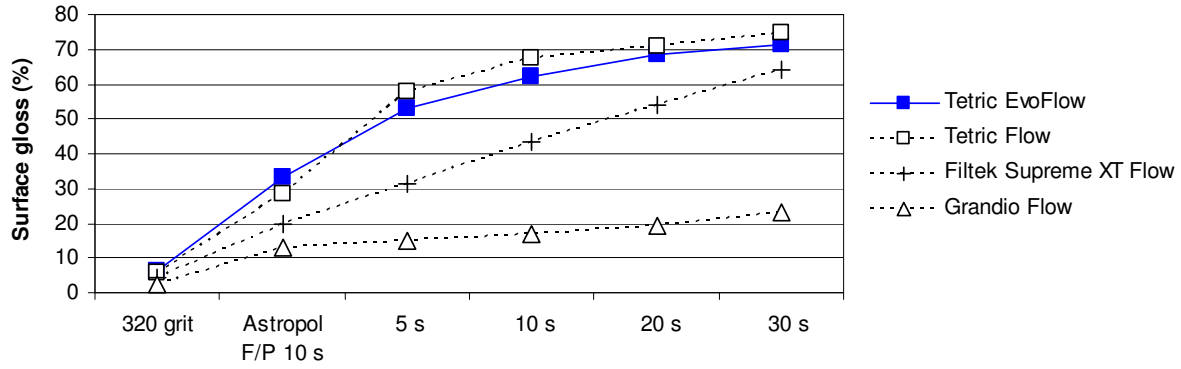


Surface roughness and gloss after prepolishing with Astropol F and Astropol P as well as after polishing to a high gloss with Astropol HP for a polishing period of up to 30 s.

The study showed that with Tetric EvoCeram a surface roughness and gloss equal to the microfilled composite Heliomolar, which is a gold standard with respect to polishability, can be obtained

The same investigation method was applied to compare Tetric EvoFlow with Tetric Flow and competitive products.



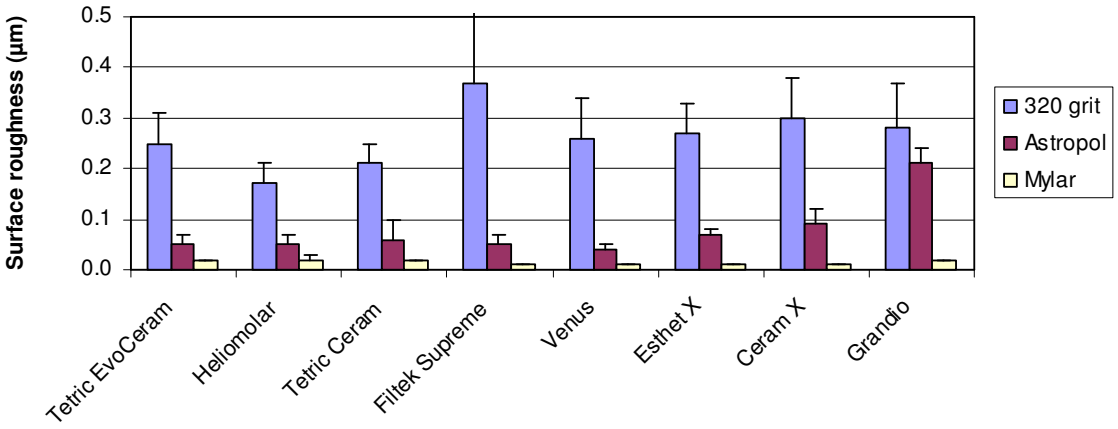


Regarding surface roughness, Tetric EvoFlow showed results after polishing with Astropol that were comparable to those achieved with Tetric Flow and Filtek Supreme XT Flowable. After 5 and 10 s of polishing with Astropol HP, the surface roughness of Tetric EvoFlow was statistically even significantly lower than that of Tetric Flow (ANOVA, $p<0.05$); this difference levelled if the polishing time was extended. As far as the surface gloss is concerned, Filtek Supreme XT Flowable test samples showed a significantly poorer performance than Tetric Flow and Tetric EvoFlow (ANOVA, post hoc Tukey B, $p<0.05$). The surface roughness and gloss of the test samples made of Grandio Flow was statistically significantly poorer than that of the other three materials.

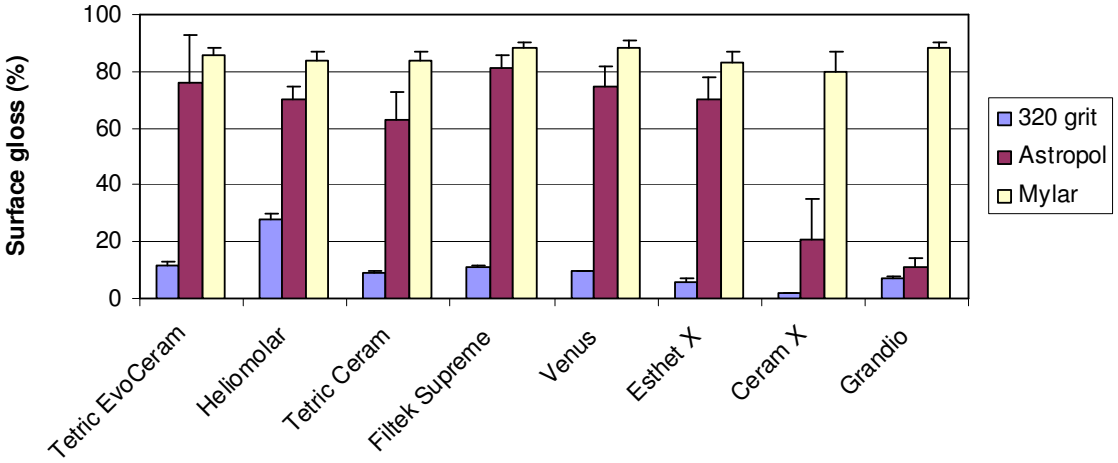
Investigation: Dr. S. Heintze, R&D Ivoclar Vivadent, Schaan, Liechtenstein

3.3 Polishing Study – University of Texas

The surface polish of eight different composites was measured after a defined polishing procedure. For each test group, eight specimens of a diameter of 12 mm and a thickness of 4 mm were prepared and cured between Mylar strips according to the manufacturer's instructions. The specimens were stored for at least 24 h at 37°C prior to further procedures. The surface roughness was measured with a profilometer (Talysurf Plus). The gloss was measured with a Novo-Curve small-area glossmeter. First, the roughness and the gloss of the surface cured against the Mylar stripes was measured as positive control, i.e., the highest achievable surface smoothness. Then, the specimens were initially finished using grinder at 320 grit at a speed of 120 rpm with water cooling for 60 s. This surface was the reference, from which polishing started. Each specimen was polished under water cooling by a single operator using an electric handpiece at 10,000 rpm for 30 s for each polishing step, i.e., Astropol F, Astropol P and Astropol HP.



Surface roughness after grinding specimens with 320 grit (negative control), polishing (test) and when polymerized against Mylar strips (positive control)



Surface gloss after grinding specimens with 320 grit (negative control), polishing (test) and when polymerized against Mylar strips (positive control)

Investigators: Dr. Leslie Roeder and Prof. Dr. John Powers, University of Texas, Huston

The study showed that with Tetric EvoCeram a surface roughness and gloss equal to the microfilled composite Heliomolar, which is a gold standard with respect to polishability, can be obtained.

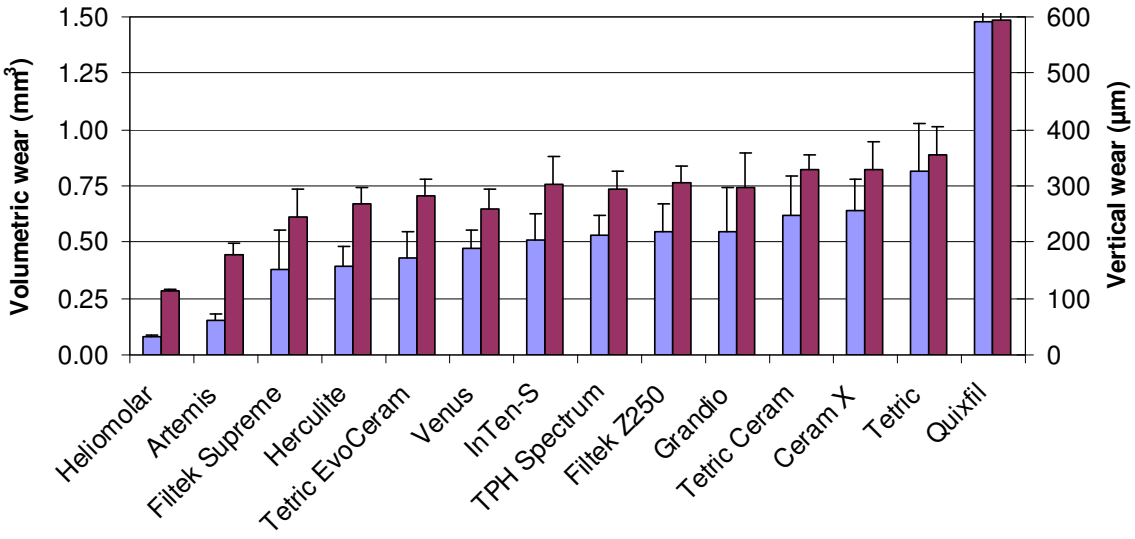
3.4 Wear in Willytec chewing simulator with Empress antagonists

The wear behaviour of restorative and prosthetic materials constitutes a vital parameter in the prospects of a restoration or prosthetic reconstruction. Wear processes affect the aesthetic appearance and masticatory function of dental restorations. Various types of wear mechanisms come into play in the oral environment; they often occur simultaneously: attrition (two-body wear), abrasion (three-body wear with the food bolus or tooth paste acting as the abrasive agent), erosion (chemical degradation) and fatigue/abfraction (chipping off due to crack formation).

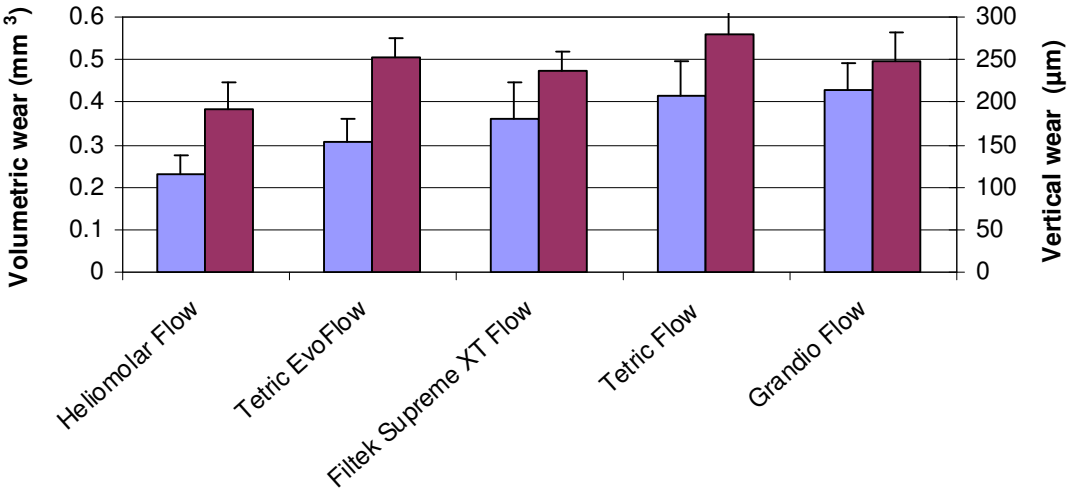
Measuring the wear of dental materials *in vivo* involves lengthy, inaccurate procedures. Even if high-precision impression materials are utilized, the restorations need to be worn for at least 12 to 24 months until the actual wear exceeds the mean variation of measurements by a large enough margin to allow the rate of wear to be evaluated. For these reasons, dental

materials are subjected to *in vitro* simulations of mastication processes to estimate their stability under clinical conditions.

Ivoclar Vivadent uses a Willytec chewing simulator to measure the wear resistance of restorative materials. Standardized antagonists made of Empress material are used to keep the data variance at a minimum. Plane test samples are subjected to 120,000 masticatory cycles, applying a force of 50N and a sliding movement of 0.7 mm. An abrasive medium is not used in this two-body wear testing method. The vertical substance loss and volume loss are measured by means of a 3D laser scanner.



Volume loss and vertical substance loss of highly viscous composite materials. The results are ranked according to volume loss, starting with the lowest measurement.



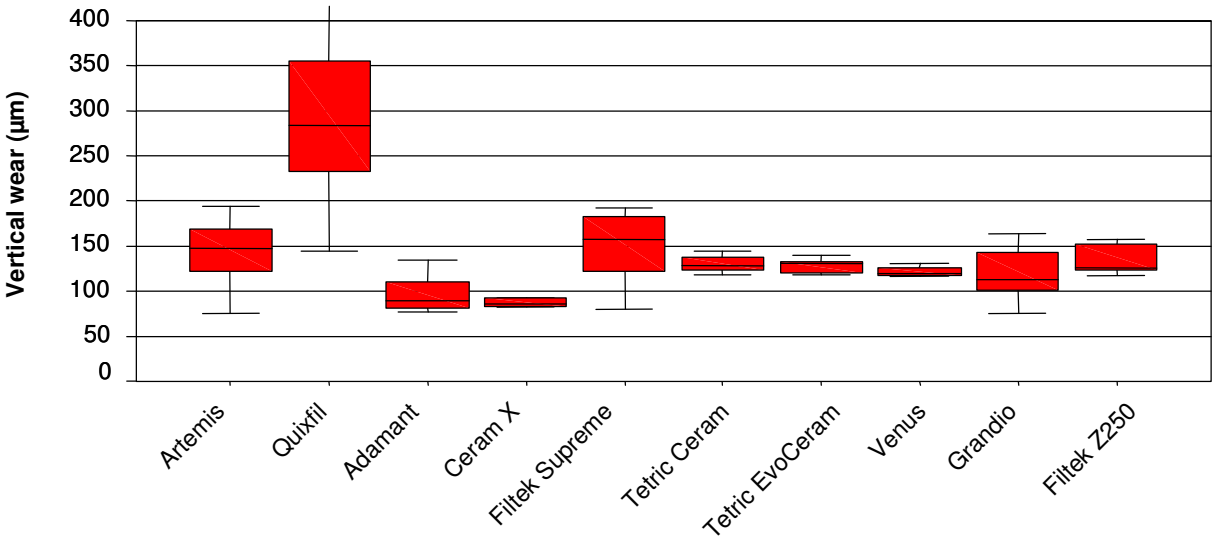
Volume loss and vertical substance loss of flowable composite materials. The results are ranked according to volume loss, starting with the lowest measurement.

Both Tetric EvoCeram and Tetric EvoFlow exhibit an improved wear resistance compared to their predecessor products Tetric Ceram and Tetric Flow, respectively.

Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.5 Pin-on-Block Wear

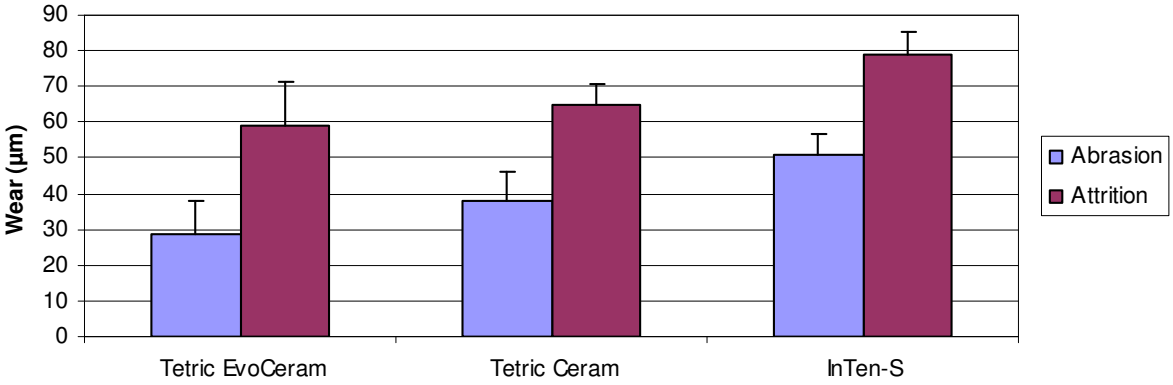
Using a similar method, the University of Regensburg determined the wear of Tetric EvoCeram and other composites. After curing and polishing with 1000 grit sand paper, the samples were exposed to the "Regensburg" masticatory simulator. In the process, the samples were loaded with a steatite ball of a diameter of 5 mm at a force of 50 N. Upon contact with the steatite antagonist, the latter made a lateral movement of 1 mm. 120,000 loading cycles were run while the samples were thermocycled between 5°C and 55°C in a 2-minute rhythm. Finally, impressions were taken and the wear was determined with gypsum replicas using a 3D laser scanner (Willytec). According to this method, most materials are equivalent with respect to wear resistance.



Investigation: Martin Rosentritt, University of Regensburg, Germany

3.6 OHSU wear testing

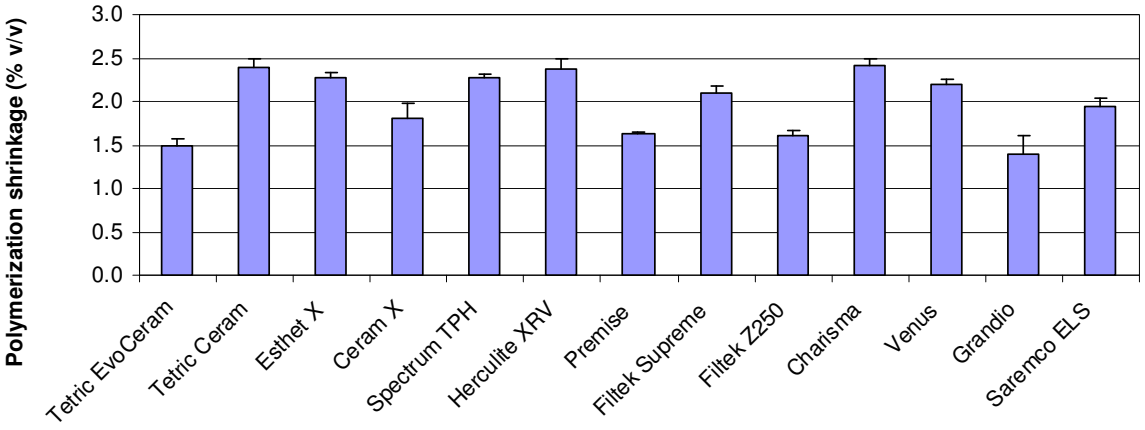
The OHSU wear testing method has been developed by Condon and Ferracane {Condon, 1996 #1392}. It became one of the most often used wear simulations used to predict oral wear of dental restorative materials. Three-body wear of Tetric EvoCeram was determined after 100,000 cycles with a slurry of PMMA and poppy seeds. The abrasion load was approximately 18 N and the attrition load approximately 80 N.



Investigation: Dr. Jack Ferracane, Oregon Health Science University, Portland, Oregon

3.7 Polymerization shrinkage - mercury dilatometer

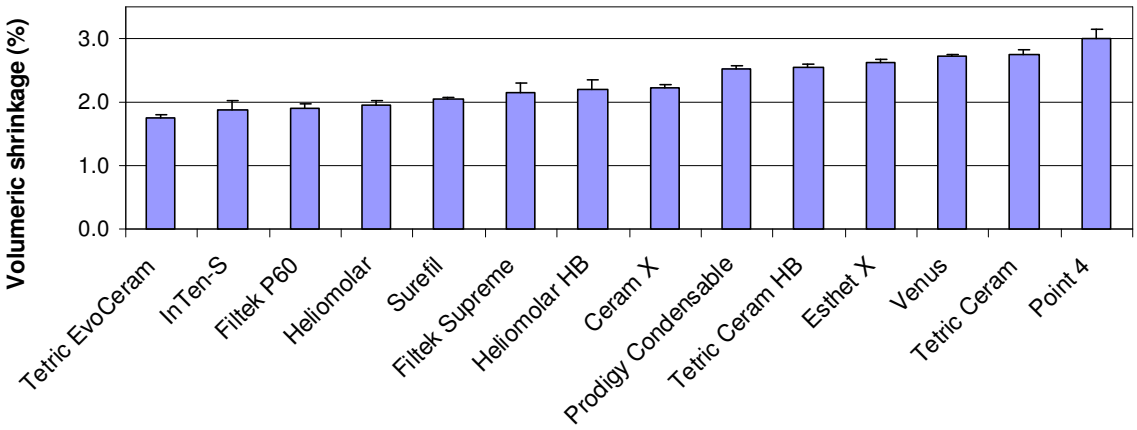
Low shrinkage results in less stress on the adhesive bond and lower deformation of the tooth structure during polymerization. This results in better margin quality. Therefore, polymerization shrinkage in vol% after 1 hour was measured with a mercury dilatometer.



Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.8 Polymerization shrinkage – buoyancy measurement

The polymerization shrinkage was also measured with a buoyancy technique. For this purpose, a specimen of a diameter of 5 mm and a thickness of 2 mm is placed in silicone oil and subsequently cured. The shrinkage is estimated by the increase of the density of the specimen during and up to 60 minutes after curing.

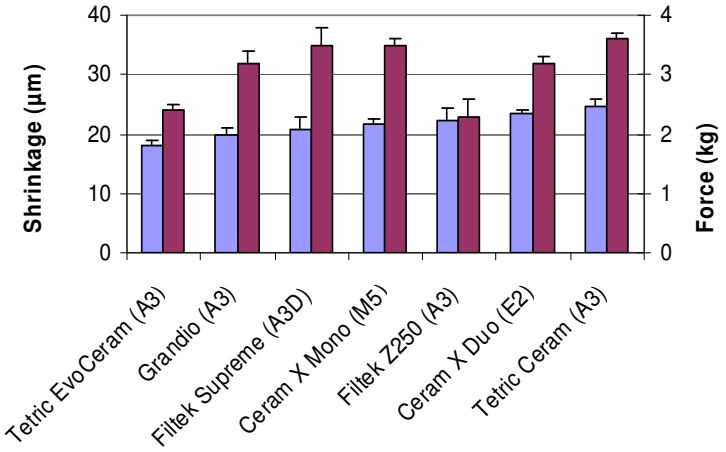


Investigator: Dr. Raimund Jaeger, Christof Koplin. Fraunhofer Institute, Germany

3.9 Polymerization shrinkage - linometer

To measure the linear polymerization shrinkage, a composite layer of a size of 50 mm^2 and a thickness of 1 mm was applied between an aluminium plate and a glass plate and then light-cured through the glass plate for 60 seconds, using a light intensity of 500 mW/cm^2. The shrinkage path was measured with infrared light for a period of 180 seconds.

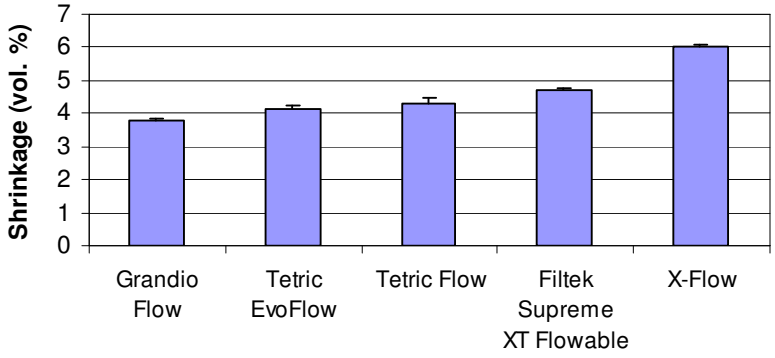
To measure the shrinkage stress, a 1.5 mm thick composite layer was polymerized in a mould measuring 8 mm in diameter. The forces created in the process were measured by means of a measuring cell and converted into kilograms.



Shrinkage path (bars on the left) shrinkage force (bars on the right) of selected composites. Study: Prof. Ivo Krejci, University of Geneva, Switzerland

3.10 Polymerization shrinkage - flowable composites

Flowable composites feature a higher content of monomer than mouldable composites with a medium viscosity. Since only the monomer content shrinks during polymerization, the shrinkage of flowable composites is thus in general higher than that of medium- or high-viscosity materials. The following diagram shows the volume shrinkage values of some flowable composites.



The polymerization shrinkage was determined using the ”bonded-disk“ technique {Watts, 1991 #200}.

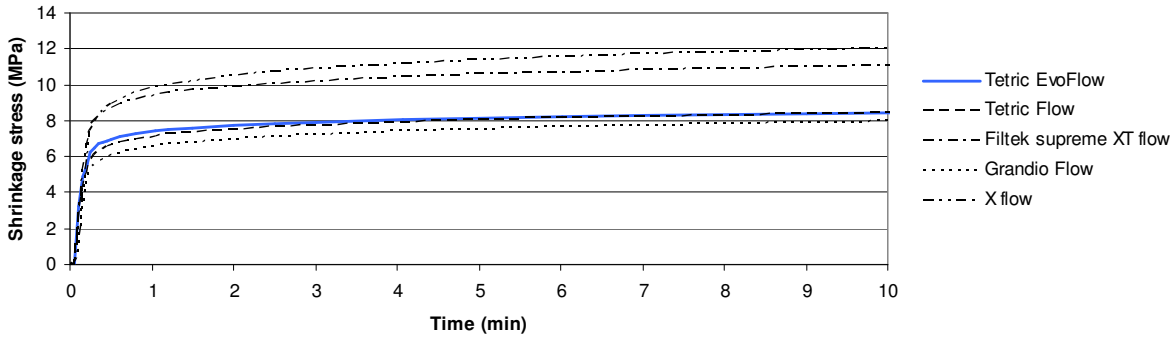
Investigation: Dr. David Watts, University of Manchester, UK (data on file).

The results show that the shrinkage of Tetric EvoFlow could be slightly reduced compared to Tetric Flow. The differences between most of the materials are relatively low if compared to the differences between medium-viscosity composites.

3.11 Shrinkage stress - flowable composites

If a composite material is polymerized as a free test sample, it can readily polymerize towards its center of mass. However, this is not the case with a filling in a tooth. A large portion of the surface of the restorative material is bonded to the tooth structure by means of an adhesive. Hence, a material is no longer able to shrink freely under such conditions. Consequently, stress is built. In tooth fillings, these shrinkage stresses result in cusp movement, particularly with large cavities {Suliman, 1993 #750}.

It is generally assumed that a low shrinkage stress results in an improved marginal quality. In very severe cases, the shrinkage during polymerization of a filling may result in cracks in the tooth structure. The figure below shows the course of shrinkage stress of a flowable composite over 10 min.



The shrinkage stress was measured with test samples with a diameter of 10 mm and a thickness of 0.8 mm using a method that has been developed at the University of Manchester {Watts, 2003 #8383}. The material was polymerized for 10 s in the HIP mode of Astralis 10 (1200 mW/cm^2). The shrinkage stress of Tetric EvoFlow is one of the lowest among flowable composites, which results in a reduced load of the adhesive bond during polymerization.

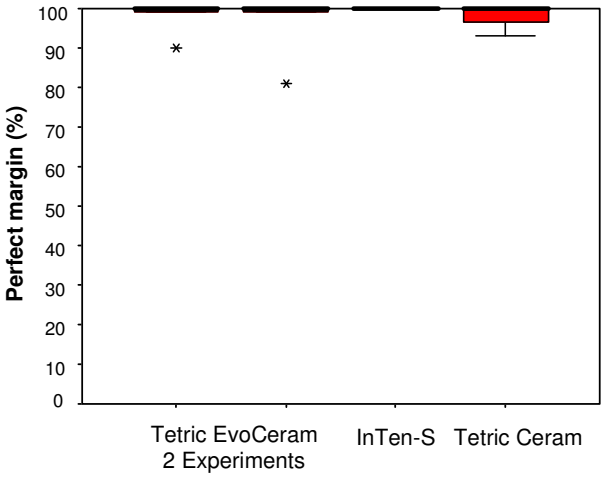
Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.12 Marginal behaviour in cylindrical dentin cavities

The occurrence of marginal gaps can lead to postoperative sensitivities, marginal discoloration and secondary caries. Both the adhesive and the composite used can have an effect on the marginal quality. Therefore, in vitro tests on the marginal quality are used to test the performance of new adhesives and composite materials.

Cylindrical cavities of a diameter of 3 mm and a depth of 2.5 mm are prepared in bovine dentin. These cavities are treated with a dentin adhesive and restored with a composite material. After polishing, the specimens are stored for 24 h in deionised water at 37°C. Finally, impressions are taken to evaluate the marginal quality. The results are expressed as the % of margin showing gaps compared to the total margin length.

Experience gathered in the testing of many adhesives and composites shows that with this test method, more than 80% perfect margin can be considered as good marginal quality, 60-80% as fair marginal quality and below 60% perfect margin as bad marginal quality.



Using the self-etching two component adhesive AdheSE, cylindrical cavities in bovine dentin were restored with Tetric EvoCeram.

It can be seen that Tetric EvoCeram provides a comparable marginal quality as InTen-S. The margins obtained with Tetric Ceram are excellent, but statistically worse than those obtained with Tetric EvoCeram and InTen-S.

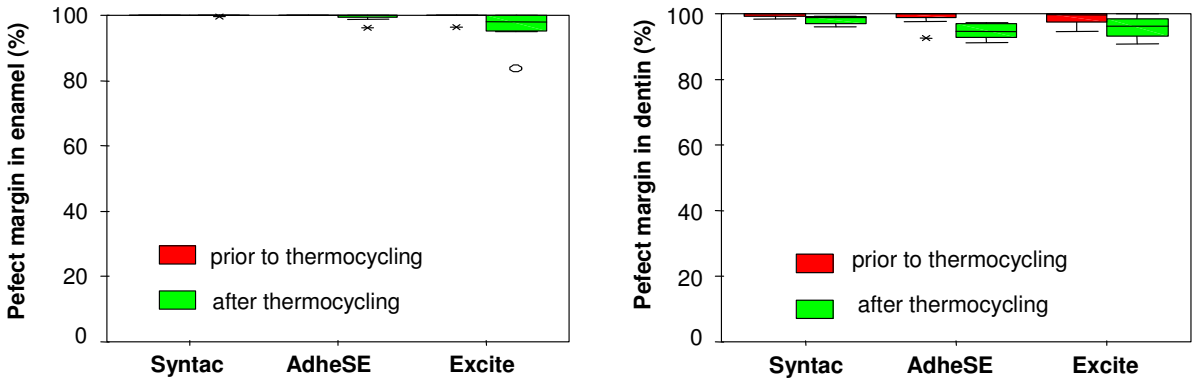
Investigation: R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

3.13 Marginal quality in Class V cavities

Investigations of marginal adaptation aim at evaluating *in vitro* the type of marginal quality that can be attained in clinical applications. For this purpose, extracted teeth are restored

with the materials to be tested. Then, impressions of the samples are taken and the marginal quality is assessed on the basis of these impressions. The samples may also be subjected to thermocycling or cyclical mechanical loading to simulate masticatory forces.

Artificial Class V defects were prepared with a diamond bur such that the coronal margin was in enamel and the cervical margin in dentin. Subsequently, they were restored using different adhesives (Syntac, AdheSE, Excite) and Tetric EvoCeram. The results show that an excellent marginal quality was attained in both the dentin and enamel for each test group. Thermocycling with 2000 cycles between 5 and 55 °C did not result in any significant deterioration of the marginal quality.



Investigation: Dr. Uwe Blunck, Charité, Berlin, Germany

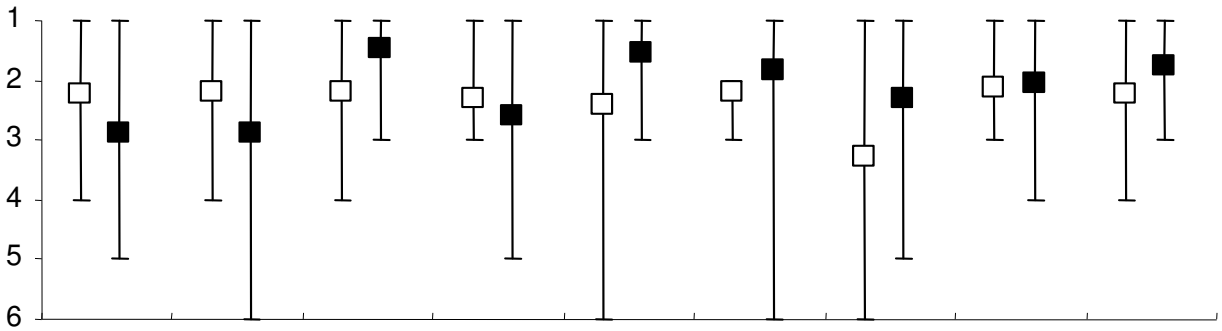
3.14 Handling evaluation by practitioners

The handling properties of dental composite resins are a key factor for both the success of a product in the marketplace and the clinical performance. Therefore, the highest priority of the development of Tetric EvoCeram has been given to match the appreciated handling properties of Tetric Ceram. Three handling evaluations were conducted during continuing education courses at the University of Erlangen in Germany. During these three continuing education courses, Tetric EvoCeram was compared in pairs with other dental composite materials.

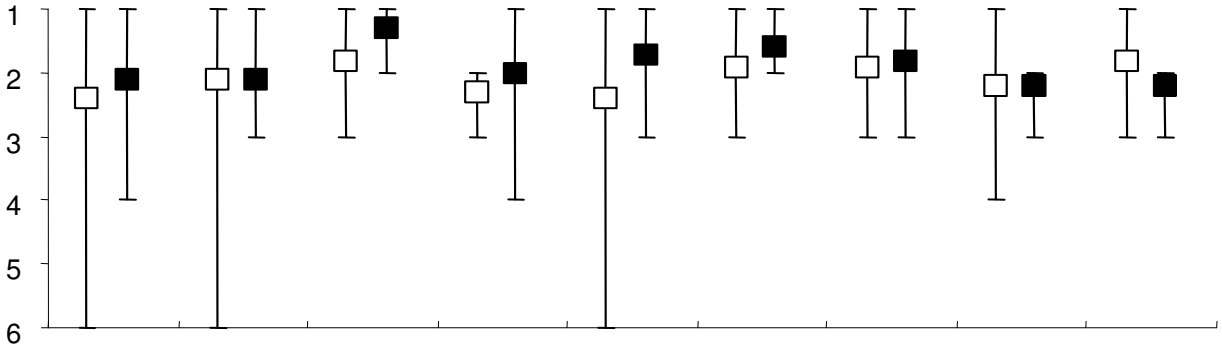
All materials were provided in compules of the shade A3. In a phantom praxis, Class I and II restorations were placed in extracted human molars under clinical conditions. According to the German school grading system practitioners rated the materials between 1 (best grade) and 6 (worst grade) with respect to the following properties:

1. How easy can the material be placed into the cavity? (Application)
2. How easy can it be sculpted? (Sculpting)
3. Non-slumpiness? (Stability)
4. How easy can the material be adapted to the cavity walls? (Adaptation)
5. Does stickiness to the instrument impair sculpting? (Stickiness)
6. Is the material homogenous bubble-free after sculpting? (Homogeneity)
7. Does the sensitivity to ambient light impair the application? (Light-sensitivity)
8. How easy can the material be finished with rotary instruments? (Finishing)
9. How easy can the material be polished (Polishability)

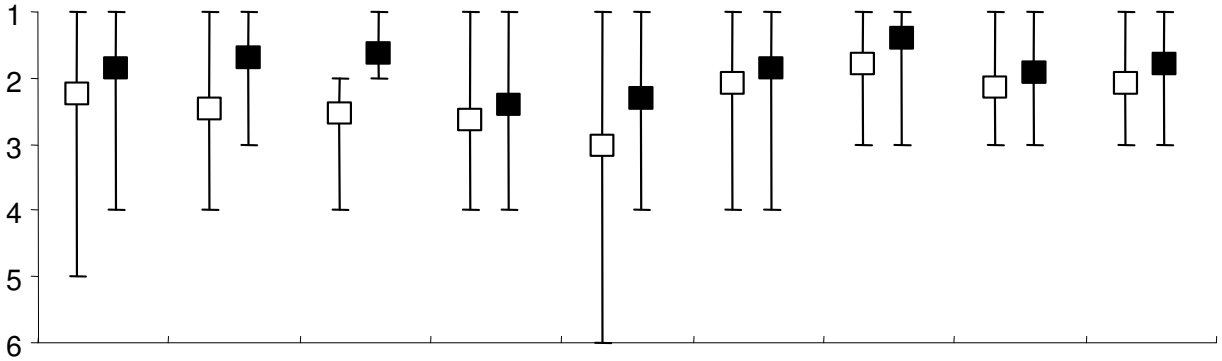
The results of these handling evaluations are presented in the graphs below. The mean grade is shown by the points and the lowest and highest grades given by an evaluator are indicated with the error bar.



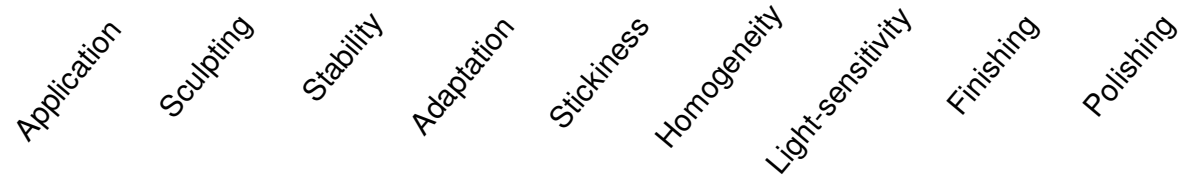
Tetric Ceram (open symbols) and Tetric EvoCeram (closed symbols). 1 is the best and 6 the worst possible rating.



Filtek Supreme (open symbols), Tetric EvoCeram (closed symbols)



Ceram X mono (open symbols, Tetric EvoCeram (closed symbols)



The comparison of Tetric EvoCeram with Tetric Ceram did not yield clear results. The comparisons with Filtek Supreme and Ceram X showed significant differences. Tetric EvoCeram was rated equal or better than Filtek Supreme in all criteria except polishability. Furthermore, Tetric EvoCeram was rated better than Ceram X in all handling criteria evaluated by the practitioners.

Investigation: M. Taschner, Dr. N. Krämer, University of Erlangen, Germany

4. Clinical Studies

4.1 Prof. Dr. Paul Lambrechts, University of Leuven, Belgium

Experimental: The objective of this study was to achieve a three-dimensional analysis of posterior restorations/tooth surfaces from replicas. Pairs of Tetric EvoCeram and Tetric Ceram restorations were compared *in situ* in approximately 15 patients. The restorations were placed using the self-etching adhesive AdheSE and evaluated at baseline and after 6, 12, 24, 36, 48 and 60 months. Volumetric and topographic changes of the restorations and tooth surfaces were quantified by means of 3D laser scanning technology and SEM evaluation of replicas.

Seventeen Tetric EvoCeram and 16 Tetric Ceram restorations were placed in the period from November to December 2003. Since then, the baseline evaluation and the recall evaluations (at 6, 12, 24, 36, 48 and 60 months) have been completed. The clinical data according to USPHS criteria are listed below.

Results:

Tetric EvoCeram	**Baseline**	**6 months**	**12 months**	**24 months**	**36 months**	**48 months**	**60 months**
Anatomical form	100%A	100%A	100%A	100%A	100%A	100%A	100%A
Secondary caries	100%A	100%A	100%A	100%A	100%A	100%A	100%A
Shade match	88%A, 12%B	88%A, 12%B	76%A, 24%B	76%A, 24%B	59%A, 41%B	47%A, 53%B	41%A, 59%B
Retention	100%A	100%A	100%A	100%A	100%A	100%A	100%A
Marginal adaptation	100%A	82%A, 18%B	76%A, 24%B	53%A, 47%B	6%A, 94%B	6%A, 94%B	6%A, 94%B
Polish	76%A, 24%B	65%A, 35%B	59%A, 41%B	47%A, 53%B	24%A, 76%B	18%A, 82%B	12%A, 88%B
Surface discolouration	100%A	94%A, 6%B	88%A, 12%B	88%A, 12%C	76%A, 24%B	76%A, 24%C	94%A, 6%C
Postoperative sensitivity	0%	0%	0%	0%	0%	0%	0%
Tetric Ceram	**Baseline**	**6 months**	**12 months**	**24 months**	**36 months**	**48 months**	**60 months**
Anatomical form	100%A	100%A	100%A	100%A	100%A	100%A	94%A, 6%C
Secondary caries	100%A	100%A	100%A	100%A	100%A	100%A	94%A, 6%C
Shade match	69%A, 31%B	69%A, 31%B	56%A, 44%B	44%A, 56%B	25%A, 75%B	19%A, 81%B	13%A, 81%B, 6%C
Retention	100%A	100%A	100%A	100%A	100%A	100%A	94%A, 6%B
Marginal adaptation	100%A	63%A, 37%B	56%A, 44%B	44%A, 56%B	19%A, 81%B	13%A, 87%B	7%A, 87%B, 7%C
Polish	25%A, 75%B	19%A, 81%B	100%B	6%A, 94%B	6%A, 94%B	100%B	94%B, 6%C
Surface discolouration	100%A	100%A	100%A	100%A	94%A, 6%C	94%A, 6%C	94%A, 6%C

Postoperative sensitivity	13%	0%	0%	0%	0%	0%	0%

Conclusion: No restorations were lost during the study period; one Tetric Ceram restoration had to be replaced while none of the Tetric EvoCeram restorations needed replacement.

After they had been *in situ* for a few years, B-ratings for marginal adaptation were more frequently observed in both Tetric Ceram and Tetric EvoCeram restorations. Similar observations occurred in other studies with self-etching adhesives. With a high degree of probability, the type of adhesive chosen to place the restorations is responsible for these ratings rather than the restorative material. In spite of these ratings, none of the Tetric EvoCeram restorations showed any signs of secondary caries.

After having been *in situ* for 5 years, 14 of the 16 Tetric Ceram restorations were clinically acceptable, which corresponds to a rate of 87%; the Tetric EvoCeram restorations achieved an excellent rate of 94%.

Likewise, the anatomical form of all Tetric EvoCeram restorations were given A-ratings after a 5-year service life and the proximal contact points had been preserved in 93% of all cases.

On the whole, the data gained in this study show that Tetric EvoCeram exhibits excellent clinical performance even after having been in place for several years.

4.2 Dr. Carlos Munoz, Dr James Dunn, Loma Linda University, California, USA

Experimental: Forty-two anterior restorations, including direct veneers, were placed with Tetric EvoCeram to treat Class III and IV defects in central and lateral incisors and canines, damaged incisal edges and diastemata. ExciTE was used as bonding agent. Both the adhesive and composite materials were light-cured using a bluephase high-performance LED curing light.

The study was commenced in April 2004. By September 2005, 33 restorations were evaluated after they had been *in situ* for 12 months. Twenty restorations were evaluated at the 3-year recall and 22 restorations were available for examination at the 5-year recall.

Results:

Tetric EvoCeram	Baseline	12 months	36 months	60 months
Anatomical form	100%A	100%A	100%A	95%A, 5%D*
Shade match	100%A	76%A, 24%B	100%A	100%A
Marginal adaptation	100%A	100%A	100%A	100%A
Marginal discolouration	100%A	94%A, 6%B	90%A, 10%B	91%A, 9%B
Surface discolouration	100%A	85%A, 15%B	100%A	100%A
Secondary caries	100%A	100%A	100%A	100%A
Surface polish	100%A	61%A, 39%B	90%A, 10%B	59%A, 32%B, 9%C
Retention	100%A	100%A	100%A	100%A

After 5 years, none of the restorations examined had been lost; all restorations were rated clinically acceptable.* The incisal edge of one veneer was slightly cracked; however, the fracture did not adversely affect the marginal integrity of the veneer and replacement was therefore not required.

None of the patients complained about postoperative sensitivity or showed any untoward gingival tissue responses at any one point during the recall evaluations.

On the basis of the results after 5 years, it can be said that Tetric EvoCeram is a good clinical choice for anterior restorations, as it maintains its excellent physical and esthetic properties over time.

4.3 Prof. Dr. Antonio Cerutti, University of Brescia, Italy

Experimental: *In vitro* studies appear to suggest that light-curing at a high light intensity may lead to a higher degree of marginal gap formation than light-curing at a low light intensity. However, these results have never been borne out by experience in the clinical practice, where high light intensities are preferred because they help save time. To examine the effect of high light intensities in clinical applications, a sample of patients received each two Class I or Class II Tetric EvoCeram/Excite restorations, one of the restorations was cured for 20 s per increment with a light intensity of 650 mW/cm^2 and the other one for 10 s per increment with a light intensity of 1200 mW/cm^2 in line with the principles of a split-mouth design.

The first restorations were placed in March 2004. Since then, a 4-year report has been completed; all 100 restorations were available for assessment at the 4-year recall.

The results of the 5-year recall were submitted for publication.

Results:

20 s, 650 mW·cm^{-2}	Baseline	6 months	12 months	24 months	36 months	48 months
Marginal adaptation	94%A, 6%B	94%A, 6%B	92%A, 8%B	88%A, 12%B	86%A, 14%B	86%A, 14%B
Marginal discolouration	98%A, 2%B	98%A, 2%B	98%A, 2%B	94%A, 6%B	94%A, 6%B	90%A, 10%B
Anatomical form	90%A, 10%B	90%A, 10%B	90%A, 10%B	90%A, 10%B	90%A, 10%B	90%A, 10%B
Secondary caries	100%A	100%A	100%A	100%A	100%A	100%A
Shade match	88%A, 12%B	88%A, 12%B	86%A, 14%B	86%A, 14%B	86%A, 14%B	86%A, 14%B
Surface texture	88%A, 12%B	90%A, 10%B	90%A, 10%B	90%A, 10%B	90%A, 10%B	90%A, 10%B
Retention	100%A	100%A	100%A	100%A	100%A	100%A

10 s, 1200 mW·cm^{-2}	Baseline	6 months	12 months	24 months	36 months	48 months
Marginal adaptation	94%A, 6%B	94%A, 6%B	94%A, 6%B	94%A, 6%B	92%A, 8%B	90%A, 10%B
Marginal discolouration	100%A	100%A	100%A	100%A	94%A, 6%B	90%A, 10%B
Anatomical form	94%A, 6%B	94%A, 6%B	94%A, 6%B	94%A, 6%B	94%A, 6%B	94%A, 6%B
Secondary caries	100%A	100%A	100%A	98%A, 2%B	98%A, 2%B	98%A, 2%B
Shade match	86%A, 14%B	86%A, 14%B	86%A, 14%B	86%A, 14%B	86%A, 14%B	86%A, 14%B
Surface texture	94%A, 6%B	88%A, 12%B	94%A, 6%B	94%A, 6%B	94%A, 6%B	94%A, 6%B
Retention	100%A	100%A	98%A, 2%B	98%A, 2%B	98%A, 2%B	98%A, 2%B

Conclusion: The main objective of this study was to compare the marginal quality of restorations that had been cured using different curing parameters. The study results observed to date clearly show that the marginal quality of the restorations does not depend on the light intensity and that both curing versions tested in this study resulted in clinically successful restorations. A significant difference in the marginal quality was not observed in any of the two versions, even not after 4 years.

Furthermore, the results of the criteria examined in this study attest to the fact that his material exhibits excellent clinical performance in posterior restorations.

4.4 Dr. Arnd Peschke, R&D Clinic, Ivoclar Vivadent AG, Schaan, Liechtenstein

Experimental: Employees of Ivoclar Vivadent AG who required Class I or II fillings were asked to participate in a clinical study with Tetric EvoCeram. A total of 50 Class I and II cavities were treated with the etch and rinse adhesive system Syntac and Tetric EvoCeram in the course of this study. The material was polymerized with the Pulse program of the Astralis 10 curing light and the restorations were polished with Astropol.

Status: The follow-up examinations took place after 6 months, 1, 2 and 5 years. After 5 years, 34 restorations could be examined. Three cases dropped out due to a change in the prosthetic planning, the remaining drop-outs were due to the patients having moved away.

Results: After 5 years, 100% of the restorations, that were available for evaluation, were still in place; only 1 restoration (3%) had to be repaired due to minor material fractures. 38% of all restorations were in a clinically “very good” to “good” and 59% in a clinically “satisfactory” condition. The documented marginal defects affected only small portions of the total margin.

Tetric EvoCeram	Baseline	6 months	1 year	2 years	5 years[4]
Number	50	50	49	45	34
Fractured restoration	100%A	100%A	100%A	100%A	97%A, 3%C
Marginal irregularities	100%A	82%A, 18%B[1)]	84%A, 16%B[1)]	84%A, 16%B	53%A, 26%A2[2)] , 21%B[2)]
Marginal discolouration	100%A	92%A, 8%B[1)]	88%A, 12%B[1)]	82%A, 18%B	46%A, 12%A2[2)], 42%B[2)]
Marginal gaps	100%A	100%A	98%A, 2%B	98%A, 2%B	88%A, 9%A2[1)], 3%B[1)]
Insufficient amount of material	100%A	98%A, 2%B	100%A	100%A	100%A
Surface texture	100%A	84%A, 16%B[3)]	88%A, 12%B[3)]	87%A, 13%B	15%A, 50%A2, 35%B
Secondary caries	100%A	100%A	100%A	100%A	100%A
Postop. sensitivity	97%A, 3%B	100%A	100%A	100%A	100%A
Survival rate	100%A	100%A	100%A	100%	100%

1) At maximum 10% of the length of the restoration margin were affected.
2) At maximum 25% of the length of the restoration margin were affected.
3) Only small areas within the occlusal contacts were affected.
4) The FDI criteria were used for the evaluation at the 5-year recall; the restorations were therefore rated as follows: A=clinically excellent, A2=clinically good, B=clinically satisfactory, C=clinically unsatisfactory but repairable and D=clinical failure.

Conclusion: After an observation period of 5 years, all restorations, that were available for evaluation, were still in place and no absolute failure was observed. Only one restoration required minor repair work due to chipping. The combination of Tetric EvoCeram and Syntac showed a very reliable clinical performance.

4.5 Prof. Dr. van Dijken, University of Umea, Sweden – First Study

Experimental: Eight Class I and 32 Class II restorations were placed in 20 premolars and 20 molars using Tetric EvoCeram in conjunction with the adhesive ExciTE. The individual increments were applied in a maximum layer thickness of 2 - 3 mm and cured for 40 s with an Astralis 7 curing light in the HIP setting.

All restorations were placed by the end of May 2003. Thirty-nine of the 40 restorations were evaluated after 12 and 24 months. Thirty-eight restorations were available for evaluation at the final 3-year recall.

Results:

	Baseline	1 year	2 years	3 years
Marginal adaptation	100%A	87%A, 13%B	87%A, 10%B, 3%D	79%A, 18%B, 3%D
Marginal discolouration	100%A	97%A, 3%B	95%A, 5%B	86%A, 14%B

Anatomical form	95%A, 5%B	92%A, 8%B	92%A, 5%B, 3%D	94%A, 3%B, 3%D
Secondary caries	100%A	97%A, 3%C	94%A, 6%C[2)]	92%A, 8%C
Surface roughness	100%A	97%A, 3%B	97%A, 3%B	100%A
Postop. sensitivity	100%A	100%A	100%A	100%A
Survival rate	100%A	97%A, 3%C	95%A, 5%C	92%A, 8%C

Conclusion: During the 3-year observation period, a total of 3 restorations were rated unacceptable because of secondary caries. This translates into an annual failure rate of only 2.6%. The stable marginal conditions and excellent surface texture which the restorations have retained over the years are particularly favourable attributes of Tetric Evo Ceram.

4.6 Prof. Dr. van Dijken, University of Umea, Sweden – Second Study

Experimental: Sixty-two Tetric EvoCeram and 62 Tetric Ceram restorations were placed in 52 patients according to the split-mouth design. The adhesive ExciTE was utilized to insert the restorations. The distribution and size of the restorations are given in the table below. All teeth treated were vital and had opposing and adjacent tooth contact. The individual increments were placed in a maximum layer thickness of 2 - 3 mm and light-cured for 20 s using an Astralis 7 curing unit in the HIP setting.

Surfaces	**Tetric EvoCeram**		**Tetric Ceram**	
	Premolar	Molar	Premolar	Molar
1 surface	-	3	-	3
2 surfaces	13	19	14	26
3 surfaces	10	8	10	3
>3 surfaces	4	5	3	3
Total	27	35	27	35

The initial (baseline) situation was evaluated two weeks after the restorations had been placed. The 36-month recall evaluation was completed in December 2006.

Results:

Tetric EvoCeram	**Baseline**	**12 months**	**24 months**	**36 months**
Anatomical form	96%A, 4%B	93%A, 7%B	93%A, 3%B, 3%D	93%A, 2%B, 5%D
Marginal adaptation	100%A	90%A, 10%B	89%A, 8%B, 3%D	81%A, 14%B, 5%D
Marginal discolouration	100%A	100%A	98%A, 2%B	98%A, 2%B
Secondary caries	100%A	100%A	98%A, 2%C	98%A, 2%C

Surface roughness	100%A	100%A	100%A	98%A, 2%B
Postop. sensitivity	98%A, 2%B	100%A	100%A	100%A
Tetric Ceram	**Baseline**	**12 months**	**24 months**	**36 months**
Anatomical form	98%A, 2%B	93%A, 7%B	93%A, 7%B	90%A, 7%B, 3%D
Marginal adaptation	100%A	90%A, 10%B	90%A, 10%B	88%A, 10%B, 2%D
Marginal discolouration	100%A	98%A, 2%B	93%A, 7%B	95%A, 2%B, 3%C
Secondary caries	100%A	100%A	100%A	98%A, 2%C
Surface roughness	100%A	100%A	100%A	100%A
Postop. sensitivity	100%A	100%A	100%A	100%A

Conclusion: The handling characteristics of Tetric EvoCeram were rated to be 'good' and 'easy to adapt'. The material appeared to exhibit slightly more stability during the contouring phase compared to Tetric Ceram. The restorations demonstrated a smooth surface finish after polishing. The surface roughness was rated 'smooth' for all Tetric EvoCeram restorations but one at the 3-year recall evaluation.

Both studies conducted by Dr. Jan van Dijken show that the clinical performance of Tetric EvoCeram continues to be excellent in the medium to long term.

4.7 Dr. Christian Gernhardt, Prof. Dr. H.-G. Schaller, University of Halle, Germany

Experimental: The subject of this study was to examine the clinical performance of AdheSE One in conjunction with Tetric EvoCeram and Tetric Flow in Class I and II cavities. The primary objective was to carry out a long-term evaluation of the marginal quality and occurrence of postoperative sensitivities in restorations placed with AdheSE One. The secondary objective was to assess if the marginal quality can be improved if all surfaces of the cavity are masked with an initial layer of Tetric Flow compared to cavities that are restored with Tetric EvoCeram alone. For this purpose, 50 pairs of Class I or II cavities were restored; one of them with Tetric EvoCeram only, while the other one was restored with an initial layer of Tetric Flow, applied in a layer thickness of approx. 0.5 mm, followed by Tetric EvoCeram. Tetric EvoCeram was applied in increments of a maximum thickness of 2 mm and polymerized with a bluephase light unit in the Soft Start (SOF) setting.

All restorations were placed between April and the end of July 2006. The 6-month evaluations were completed in January 2007 and the 12-month recalls in September 2007. In November 2008, the 24-month report became available; 43 restorations were assessed at the recalls in the group without Tetric Flow and 44 restorations in the group with Tetric Flow.

Results:

without Flow	baseline	6 months	12 months	24 months
Tooth vitality	100%A	100%A	100%A	100%A
Postop. sensitivities	96%A, 4%B	100%A	100%A	100%A
Marginal irregularities	100%A	96%A, 4%B	96%A, 4%B	93%A, 7%B
Marginal discolouration	100%A	96%A, 4%B	94%A, 6%B	91%A, 9%B
Secondary caries	100%A	100%A	100%A	100%A
Surface quality	100%A	100%A	100%A	100%A
Colour fidelity	100%A	100%A	100%A	100%A
Restorative integrity	100%A	100%A	98%A, 2%B	98%A, 2%B
with Flow	**baseline**	**6 months**	**12 months**	**24 months**
Tooth vitality	100%A	100%A	100%A	100%A
Postop. sensitivities	96%A, 4%B	100%A	100%A	100%A
Marginal irregularities	100%A	94%A, 6%B	94%A, 6%B	91%A, 9%B
Marginal discolouration	100%A	98%A, 2%B	98%A, 2%B	93%A, 7%B
Secondary caries	100%A	100%A	100%A	100%A
Surface quality	100%A	100%A	100%A	100%A
Colour fidelity	100%A	100%A	100%A	100%A
Restorative integrity	100%A	100%A	96%A, 4%B	95%A, 5%B

Conclusion:

At baseline, the restorations did not show any shortcomings with regard to the following evaluation criteria: marginal discolouration, marginal adaptation, marginal gap, colour fidelity, surface quality, proximal contacts and fractures. Three patients complained about postoperative sensitivity over a period of 24 hours. The pain persisted for more than seven days in one of the patients. No considerable loss in the quality of the restorations was detected at the recall evaluations after 6, 12 and 24 months. No differences between the two test groups were noted.

After 24 months, a zero failure rate was found with regard to the evaluation criteria of vitality, hypersensitivity, secondary caries, surface quality, colour fidelity and preservation of proximal contacts.

4.8 Prof. Dr. Jürgen Geis-Gerstorfer, University of Tübingen, Germany

Experimental:

The objective of this study was to examine the wear behaviour of Tetric EvoCeram and Tetric Ceram. For this purpose, 57 Class I or II restorations were placed in 31 patients using either one of the two materials. In 25 patients, the restorations were placed adjacent to each other, which enabled a direct comparison of the two materials. The self-etching, two-step adhesive AdheSE was used as the bonding

agent. Impressions were taken at baseline as well as 3, 6, 9 and 12 months after the restorations had been inserted. Attrition of the contact areas was quantified with a 3D laser scanner.

Results: The table below shows the wear depths measured for the contact areas of the Tetric EvoCeram and Tetric Ceram restorations.

	Tetric EvoCeram		Tetric Ceram	
	Median	Range	Median	Range
3 months	110	40 - 340	120	40 - 390
12 months	170	60 - 360	170	80 - 420

The maximum values of wear depth measured in the contact areas vary to such a large degree that differences between the two materials could not be determined. From this it can be concluded that the chewing behaviour of the patient and the occlusal conditions have a far more decisive effect on the wear depth than the restorative material itself.

None of the restorations fractured or was lost during the 12-month observation period.

4.9 Dr. Mark A. Latta, Creighton University School of Dentistry, Nebraska, USA

Experimental: Fifty-five Class V restorations were placed in 28 patients using Tetric EvoCeram. The self-etching adhesive AdheSE was used as bonding agent. The materials were cured with a high-performance bluephase LED light unit.

The baseline report was completed in September 2004. Forty-five restorations in 26 patients were available for evaluation at the 12-month recall.

Results:

Tetric EvoCeram	Baseline	6 months	12 months
Shade match	93%A, 7%B	91%A, 9%B	91%A, 9%B
Marginal discolouration	100%A	86%A, 14%B	76%A, 24%B
Marginal quality	100%A	93%A, 7%B	71%A, 29%B
Secondary caries	100%A	100%A	100%A
Postop. sensitivity	100%A	100%A	100%A
Retention	100%A	100%A	100%A

Conclusion: It is noteworthy that the preoperative cervical sensitivity abated in all cases after the treatment. After 6 and 12 months, an increasing number of restorations received B-ratings for marginal discolouration. Similar results had already been observed in other studies involving self-etching adhesives. It may therefore be concluded that, in all probability, the type of adhesive material used to place the restorations was responsible for the discoloration rather than the restorative material. In the opinion of the examiner, the marginal discolouration

could have been easily polished away. However, the discolouration was not removed so that the study results would not be influenced.

The clinical performance of the material was rated excellent. Ease of handling, an outstanding shade match and rapid polishing were all commended as particularly noteworthy attributes by the clinical operators. Furthermore, the excellent high-gloss surface finish, which was noted at the baseline evaluation, was maintained at the 6- and 12-month recall evaluations.

4.10 Prof. Dr. Reinhard Hickel, Dr Jürgen Manhart, University of Munich, Germany

Experimental: Fifty-six Class I and II restorations were placed with Tetric EvoCeram and 43 with Tetric Ceram. The self-etching adhesive AdheSE was used as bonding agent. The majority of the restorations (41 Tetric EvoCeram and 32 Tetric Ceram restorations) were clinically evaluated and rated after 6 months.

Results:

Tetric EvoCeram	Baseline	6 months
Surface texture	100%A	98%A, 2%B
Shade match	100%A	100%A
Anatomical form	100%A	100%A
Marginal integrity	100%A	95%A, 5%B
Marginal discolouration	100%A	100%A
Tooth integrity	100%A	100%A
Restorative integrity	100%A	100%A
Sensitivities	100%A	98%A, 2%B
Tetric Ceram	**Baseline**	**6 months**
Surface texture	100%A	94%A, 6%B
Shade match	100%A	97%A, 3%B
Anatomical form	100%A	100%A
Marginal integrity	100%A	94%A, 6%B
Marginal discolouration	100%A	91%A, 9%B
Tooth integrity	100%A	100%A
Restorative integrity	100%A	100%A
Sensitivities	100%A	94%A, 6%B

Conclusion: Both restorative systems received excellent ratings for their clinical behaviour at the 6-month recall. Almost all criteria were given A-ratings.

5. Toxicological data

Tetric EvoCeram employs the same monomer formulation as a previous product, which was subjected to a thorough toxicological evaluation. The only difference between Tetric EvoCeram and that product is that, in addition, Tetric EvoCeram contains the inorganic filler mixed oxide. This has no impact on the toxicological properties because mixed oxide is insoluble and embedded in the Tetric EvoCeram matrix. Furthermore, mixed oxide has been employed for many years in other dental composite materials including Tetric Ceram. In order to verify the applicability of the toxicological data obtained with the previous product (InTen-S) on Tetric EvoCeram, leachables of Tetric EvoCeram have been analyzed. No significant difference was found in the amount of leachable omponents between Tetric EvoCeram and the previous product. This was confirmed by the repetition of a cytotoxicity test and a mutagenicity test with Tetric EvoCeram.

5.1 Cytotoxicity

Samples of Tetric EvoCeram were extracted in RPMI 1640 medium according to ISO 10993-12. Subsequently, L929 cells were brought into contact with this extract for 24 h. With the help of a tetrazolium dye (XTT), the vitality of the cells was measured after 24 h. No inhibition was found with undiluted extract. These findings show that no cytotoxic substances can be dissolved from Tetric EvoCeram {Meurer, 2004 #494} similar to the earlier findings {Glos, 2000 #379}.

5.2 Mutagenicity

Extracts of samples of a previous product with the same monomer composition were examined using the Ames Test {Sokolowski, 2001 #380} and the Mouse Lymphoma Assay {Wollny, 2001 #381}. None of the tests indicated any mutagenic activity. The data have been confirmed with an Ames Test with Tetric EvoCeram {Sokolowski, 2004 #493}.

5.3 Conclusions

The results on Tetric EvoCeram and the earlier results obtained with a material of the same monomer composition show that Tetric EvoCeram does not present a risk in a cured or uncured state if it is properly used. Nevertheless, the well-known sensitizing effect of methacrylates must be taken into account when treating people with a hypersensitivity to these materials. In exceptional cases, contact allergies may manifest themselves in dental staff.

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Ivoclar Vivadent AG
Research & Development
Scientific Service
Bendererstrasse 2
FL - 9494 Schaan
Liechtenstein

Contents: Dr. Urs Lendenmann / Dr. Marion Wanner
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