

SCIENTIFIC

REPORT

10 Years of Tetric Evolution



Vol. 01 / 2014

English

Tetric EvoCeram®



10 YEARS
OF CLINICAL
EVIDENCE

Tetric EvoFlow®

Tetric EvoCeram®

Tetric EvoCeram® Bulk Fill



ivoclar
vivadent®
passion vision innovation



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10 Year Anniversary – Tetric EvoCeram



New products come and go - with only a few able to establish themselves as long-term market contenders. Tetric EvoCeram has enjoyed 10 successful years on the dental market and is still considered a modern universal composite.

Due to in-house developed and patented technologies, plus an optimised combination of commercially available components, an ideal compromise between esthetics, handling properties and mechanical strength could be achieved. Prepolymer technology, was undoubtedly a key contributor to this success – involving pre-polymerised components that facilitate minimal shrinkage combined with excellent esthetics and surface properties. New in-house developments in colour pigments plus a skilful selection of fillers and organic matrix materials have led to a wide range of shades with good depth of cure. The high radiopacity and lengthy modelling-time under operatory-light can also be ascribed to patented in-house advancements.

Tetric EvoCeram Bulk Fill is a further development of Tetric EvoCeram. This bulk fill composite for the posterior region, can be applied in 4 mm increments due to the highly reactive photoinitiator Ivocerin. Together with Tetric EvoFlow, our well-established adhesives and Bluephase polymerisation lights, Ivoclar Vivadent offers an optimised direct-filling system with a broad range of applications.

The long-term success of a product is decided by the market. New technologies alone are no guarantee for commercial success. It is crucial therefore that we get relevant feedback from our customers in order to reach the right conclusions regarding properties for new products. Ongoing, close collaboration with our customers is extremely important, and on this note, I would like to take the opportunity to thank all users of the Tetric EvoCeram product-family, especially those who have sent feedback on our products over the years – whether positive or negative.

The information gathered here detailing the most important in vitro and clinical data for Tetric EvoCeram and Tetric EvoCeram Bulk Fill, will I hope encourage you and reaffirm that your product choice is the right one. I wish you continued success and enjoyment using the Tetric Evo family.

Best Regards

A handwritten signature in black ink, appearing to read 'TH HIRT', written over a light blue horizontal line.

Dr Thomas Hirt
Chief Technology Officer

The evolution of composite technology

Ivoclar Vivadent has been at the leading edge of composite development for many years. The composite success story is driven, not only by patient demand for increasingly esthetic filling materials but by continued industry-led product development with regard to the physical, esthetic and handling qualities of adhesives and composites. What was once innovation is now proven technology. The launch of Tetric EvoCeram in 2004 represented the amalgamation of numerous technologies. Tetric EvoCeram combined the knowledge gained with the prepolymer technology of Heliomolar and the experience obtained with Tetric Ceram (launched in 1997) regarding handling properties – this plus reduced polymerisation shrinkage and wear, culminated in an **Evolutionary** product based on previous outstanding and reliable products. In turn Tetric EvoCeram Bulk Fill – launched in 2011 was based on the tried and tested technology behind Tetric EvoCeram.

Tetric EvoCeram is a light-cured, universal composite for high-end direct restorations in both the anterior and posterior regions. Available in numerous enamel, dentin and bleach shades, it offers excellent esthetics and natural shade blending due to the optically coordinated light refraction indices of the fillers, monomer matrix and colour pigments. All shades can be cured in 10 seconds (light source $\geq 1000 \text{ mWcm}^2$) in layers of up to 2 mm thickness; and a patented light controller reducing sensitivity to ambient light, ensures adequate working time to model and sculpt restorations.

Tetric EvoFlow is a light-cured flowable hybrid composite with a wide range of application. It features excellent radiopacity and is suitable as an initial layer for Class I to V restorations, for Class V restorations, for composite repairs, extended fissure sealing and also the cementation of indirect ceramic or composite restorations.

Tetric EvoCeram Bulk Fill took composite technology to the next level, representing a paradigm shift in modern dentistry away from the standard composite layering technique. Based on the clinically proven Tetric EvoCeram, Tetric EvoCeram Bulk Fill is a light-cured composite for direct restorations in posterior teeth and may also be used for class V restorations, extended fissure sealing and reconstructive build-up. It has a sculptable viscosity and is designed to be applied in bulk increments of up to 4 mm, which can also be cured in 10 seconds (light source $\geq 1000 \text{ mWcm}^2$). Tetric EvoCeram Bulk Fill combines advanced composite-filler technology, a pre-polymer shrinkage stress reliever, a patented light initiator/polymerisation booster – Ivocerin, and a light sensitivity filter in order to achieve its esthetic and mechanical properties.



Since its introduction to the market, the composite material Tetric EvoCeram like its predecessors Tetric Ceram and Tetric has been widely used and accepted. Worldwide over 100 million Tetric EvoCeram restorations have been placed. Tetric EvoFlow is the best-selling flowable composite in Europe and Tetric EvoCeram Bulk Fill was named the top bulk fill composite by The Dental Advisor for both 2013 and 2014.

Many renowned experts have contributed to an expanding database of studies. The following pages compile the most important results from studies spanning 10 years of the Tetric Evo family. Its popularity is backed by a wealth of scientific data.



Studies

Tetric EvoCeram[®]



THE DENTAL
ADVISOR[™]

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Clinical performance of posterior composite restorations over 10 years

Study location: **Internal Clinic, R&D, Ivoclar Vivadent, Schaan, Liechtenstein.**

Study time period: **10 years / 2004 – 2014**

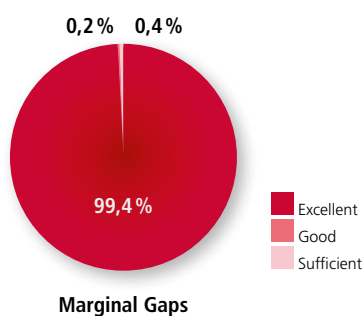
Study author(s): **A. Peschke, R. Watzke, S. Heintze**

Method:

To evaluate the long-term clinical performance of Tetric EvoCeram in posterior cavities, selected FDI criteria (Hickel et al, 2010) and a semi-quantitative clinical evaluation method (SQUACE) were employed. 50 (11 Class I and 39 Class II) cavities were restored using the total-etch adhesive system Syntac plus Tetric EvoCeram. Recalls took place after 6 months, 1, 2, 5 and 10 years. Three drop-outs were recorded due to a change in the prosthetic planning and 13 were due to a change of residence. After 10 years, 34 (68%) restorations could be assessed. The FDI-criteria included the evaluation of esthetic, functional and biological properties. Criteria concerning the restorations' marginal quality were semi-quantitatively evaluated as % of total margin length.

Results:

After 10 years, 100% of the available restorations were still in place, there was no caries or hypersensitivity and the majority were graded either "excellent" or "good" for most of the criteria. Only 2 restorations (6%) had to be repaired due to minor material chipping affecting proximal contact or margins. Documented marginal flaws affected only small portions of the total margin length. Patients themselves rated the fillings either excellent (97.1%) or good (2.9%).



Marginal Gaps

Average percentage of total margin length rated "excellent", "good" or "sufficient" with regard to marginal gaps

Summary:

100% of restorations in place with over 96% rated excellent or good in all marginal categories.

Conclusion:

The combination of Tetric EvoCeram and Syntac exhibited a reliable clinical performance after 10 years in situ and showed outstanding marginal quality.

Reference: Peschke et al 2014

The 10 year performance of Tetric EvoCeram in Class II cavities. A randomized controlled clinical study

Study location: **Dental School Umeå, Umeå, Sweden**

Study time period: **10 years / 2003 - 2013**

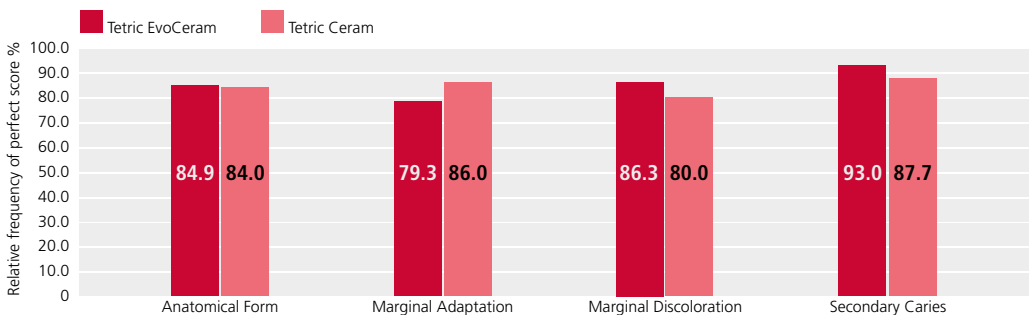
Study author(s): **J. W. V. van Dijken**

Method:

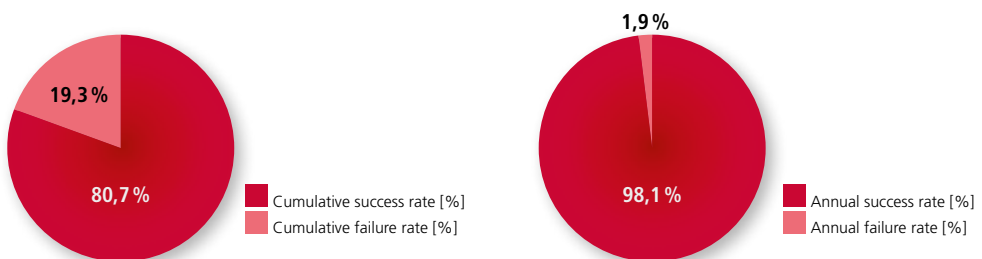
To compare the long term clinical performance of Tetric EvoCeram and Tetric Ceram in Class II cavities, 61 pairs of fillings were applied in 52 patients. Each patient received at least one Tetric EvoCeram and one Tetric Ceram restoration. Restorations were evaluated using slightly modified USPHS criteria, at baseline, after 6 months and then annually for 10 years. Scores 0 (best) to 4 (worst) were used. The following characteristics were evaluated: anatomical form, marginal adaptation, colour match, marginal staining, surface texture and secondary caries.

Results:

93% i.e. 57 restoration-pairs (114 restorations) could be evaluated after 10 years. One patient reported mild postoperative sensitivity after baseline (Tetric EvoCeram) and one tooth was extracted after 4 years due to pain (Tetric Ceram). After 10 years, both composites still exhibited a surface texture score of zero – similar to polished enamel. The 10-year scores for the other variables differed significantly from the baseline scores ($p < 0.05$) but remained high at approx. 80% or higher. There were no failures at 1 year, 14 after 6 years (8 Tetric EvoCeram and 6 Tetric Ceram) and 22 after 10 years (11 Tetric EvoCeram and 11 Tetric Ceram restorations), giving a cumulative relative frequency of 19.3% failure for both composites.



Relative frequency of perfect scores (0) by characteristic and composite



Cumulative and annual relative frequency of success (%) for Tetric EvoCeram and Tetric Ceram

Summary:

The overall success rate was therefore 80.7% for both Tetric Ceram and Tetric EvoCeram, with an annual failure rate of 1.9% for both materials. Of the failures half were due to secondary caries. No statistically significant difference in the overall survival rate between the two composites was found over the course of the study.

Conclusion:

After 10 years, both Tetric EvoCeram and Tetric Ceram exhibited a success rate of over 80% and acceptable annual failure rates, with secondary caries the principle reason for failure.

Reference: van Dijken 2014

Tetric EvoCeram: Eight-year clinical performance report

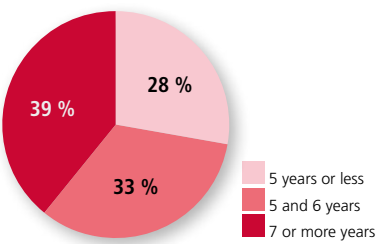
Study location: **The Dental Advisor, USA**
Study time period: **8 years**
Study author(s): **The Dental Advisor**

Method:

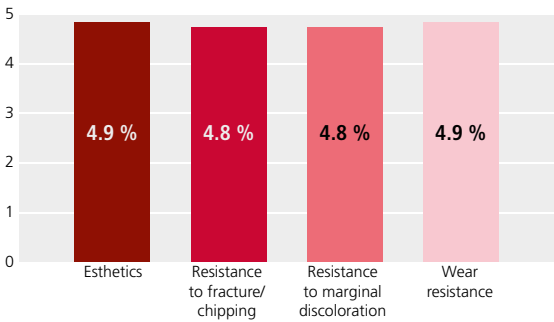
Over an eight year period, 873 Tetric EvoCeram restorations were placed and monitored. 637 of these (73%) were evaluated at the 8 year recall. 96% were posterior and 4% were anterior restorations and included Class I,II, III and IV restorations. The timeline of the restorations is shown below.

Restorations were evaluated as to: esthetics, resistance to fracture/chipping, resistance to marginal discoloration and wear resistance. A 1-5 rating scale was used for the evaluation: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent. Any restoration receiving a rating of 1 or 2 was automatically replaced.

Results:



Timeline of Tetric EvoCeram restorations in service



The Dental Advisor rating (1-5) of Tetric EvoCeram characteristics

Summary:

All criteria achieved very high ratings of 4.8 or 4.9 at the 8-year recall. With regard to esthetics, 93% received an excellent rating and 7% good to very good. 3 were replaced due to poor esthetics. For resistance to fracture/chipping, over 95% of the 637 restorations received an excellent rating; 2% had chipped but did not require replacement and 3% were replaced. 86% of the restorations showed no microleakage and were rated excellent, 13% had slight to medium microleakage and 1% needed to be replaced. 98% showed no evidence of wear and were rated excellent; 1.5% received a good or very good rating and 0.5% were replaced due to excessive wear.

Conclusion:

Tetric EvoCeram performed extremely well, receiving a 97% (5-Plus) 8-year clinical performance rating. It has excellent handling characteristics and showed superior performance in all of the criteria evaluated. As 96% of the restorations were posterior restorations it proved particularly resistant to fracture and chipping after 8 years.

Reference: The Dental Advisor 2014

Marginal quality of posterior microhybrid resin composite restorations applied using two polymerisation protocols: 5-year randomised split mouth trial

Study location: **University of Brescia, Italy**

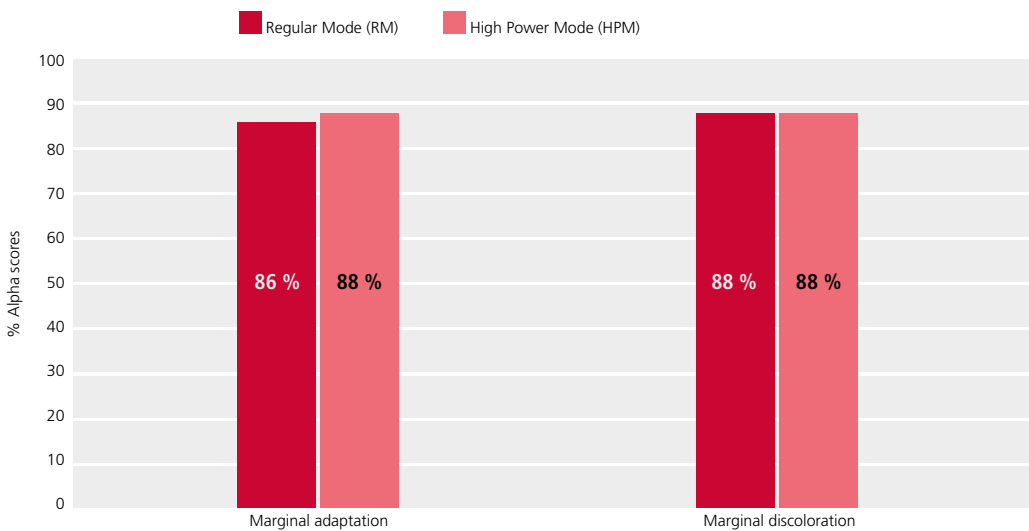
Study time period: **5 years**

Study author(s): **Barabanti N, Gagliani M, Roulet J-F, Testori T, Ozcan M, Cerutti A.**

Method:

50 patients received 2 restorations (n=100) (Class I or II) each in this split-mouth study. 36 restorations were in premolars and 64 in molars. ExcITE was used as the adhesive and Tetric EvoCeram was applied incrementally. In each patient two polymerisation protocols were employed – either curing in regular mode (RM = 650 mW/cm² for 20 s) or in high-power mode (HPM = 1200 mW/cm² for 10 s). Restorations were evaluated at baseline, after 6 months and annually thereafter as to marginal quality using modified USPHS and SQUACE criteria.

Results:



Percentage "Alpha" scores for marginal adaptation and discoloration of Tetric EvoCeram restorations using different polymerisation protocols after 5 years

Summary:

There were no drop outs after 5 years and no secondary caries, endodontic complications, fractures or chippings were observed in any of the restored teeth. Alpha scores (**USPHS**) for marginal adaptation (86% and 88% for RM and HPM respectively) and marginal discoloration (88% and 88%, for RM and HPM respectively) did not show significant differences between the two polymerisation protocols. Alpha scores (**SQUACE**) for marginal adaptation (88% and 88% for RM and HPM) and marginal discoloration (94% and 94% for RM and HPM) were also not significantly different after 5 years.

Conclusion:

After 5 years there was a survival rate of 100% for Tetric EvoCeram restorations and the type of polymerisation protocol had no significant influence on the marginal quality of Tetric EvoCeram in this 5 year study.

Reference: Barabanti et al 2013

Tetric EvoCeram in comparison to Tetric Ceram in Class I and II cavities

Study location: **University of Leuven, Belgium**
Study time period: **5 years**
Study author(s): **Palaniappan S, Elsen L, Lijnen I, Peumans M, van Meerbeek B, Lambrechts P**

Method:

17 Tetric EvoCeram and 16 Tetric Ceram restorations were placed in Class I and II cavities. The self-etch adhesive AdheSE was used for both materials. Volumetric and topographic changes of the restorations and tooth surfaces were quantified by means of 3D laser scanning technology and SEM evaluation of replicas. All restorations were available for evaluation at the 5 year recall. The clinical data was evaluated according to USPHS criteria using the Alpha, Bravo, Charlie, Delta/A,B,C,D scale.

Results:



Percentage of Tetric EvoCeram and Tetric Ceram restorations rated “Alpha-Delta” after 5 years by characteristic

Summary:

Neither product involved postoperative sensitivity. One Tetric Ceram restoration had to be replaced whereas no Tetric EvoCeram restoration required replacement. Anatomical form, secondary caries, retention and postoperative sensitivity all achieved 100% Alpha scores for Tetric EvoCeram. Tetric Ceram also achieved high scores for these characteristics. After 5 years of service, more B ratings were received by both products with regard to marginal adaptation, surface polish and colour match.

Conclusion:

After 5 years, 94% of the Tetric EvoCeram restorations were considered clinically acceptable (A or B rating) and 87% of the Tetric Ceram restorations.

Reference: Palaniappan et al 2010

Clinical evaluation of Tetric EvoCeram for anterior restorations

Study location: **Loma Linda University, California, USA**

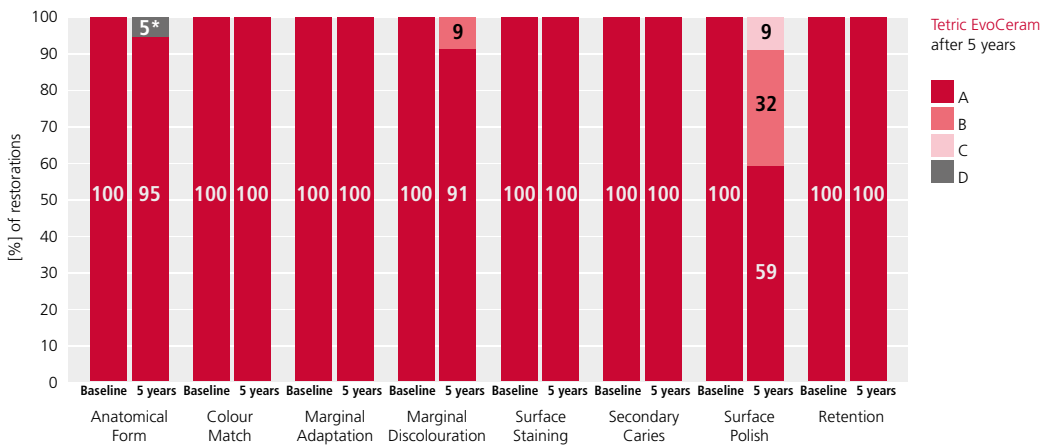
Study time period: **5 years**

Study author(s): **Lee S, Li Y. (Munoz C)**

Method:

42 anterior restorations including direct veneers, were placed with Tetric EvoCeram and Excite to treat: Class III and IV defects in central and lateral incisors and canines, damaged incisal edges and diastemata. The clinical data was evaluated using the Alpha, Bravo, Charlie, Delta/A, B, C, D scale.

Results:



Summary:

22 restorations were available for evaluation after 5 years. The retention rate was 100% after 5 years of service. 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 not deemed necessary. Neither secondary caries nor surface discoloration was observed. None of the patients complained of postoperative sensitivity.

Conclusion:

The results of this 5 year study show that Tetric EvoCeram is a good clinical choice for anterior restorations – retaining its good physical and esthetic properties over time.

Reference: Lee et al 2009

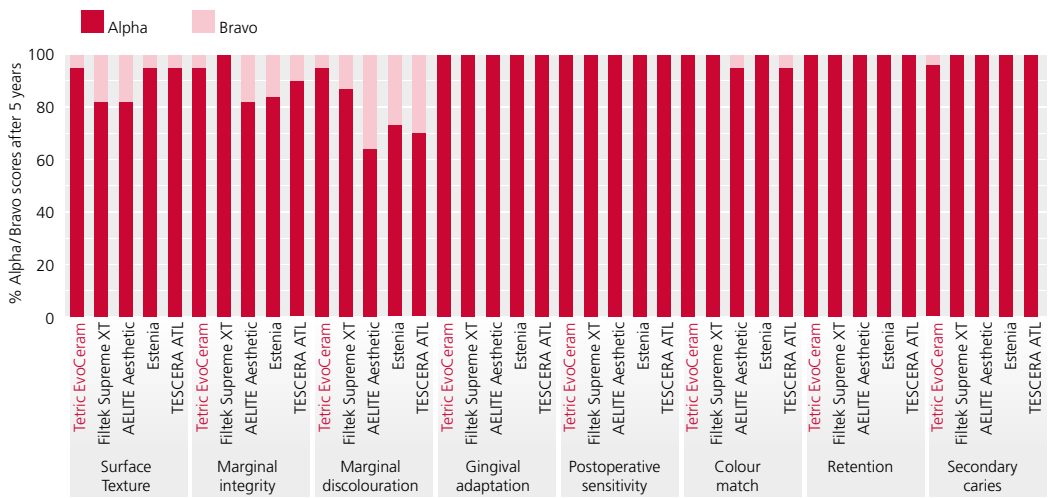
A five year clinical evaluation of direct nanofilled and indirect composite resin restorations in posterior teeth

Study location: **Selcuk University Konya, Turkey**
Study time period: **5 years**
Study author(s): **Cetin A R, Unlu N, Cobanoglu N**

Method:

To assess the clinical efficacy of posterior composite restorations placed both directly and indirectly, a total of 108 Class I or II cavities in 54 patients were restored with 3 direct composites; Tetric EvoCeram, Filtek Supreme/3M Espe and AELITE Aesthetic/Bisco and 2 indirect composites: Estenia/Kuraray and TESCERA ATL/Bisco. Restorations were evaluated by 2 examiners using modified USPHS criteria at baseline (1 week after treatment) and after 5 years.

Results:



Percentage "Alpha/Bravo" scores for various direct and indirect composites after 5 years by characteristic

Summary:

At baseline, 4% of the restorations exhibited postoperative sensitivity. This was transient except for one Estenia restoration which required root canal treatment and replacement after 2 years. After 3 years, one Tetric EvoCeram restoration was replaced due to secondary caries. At the 5-year recall, all 54 patients could be recalled and evaluated. The graph shows the 5 year, Alpha and Bravo Scores, as none of the composites scored lower than this for any criteria i.e. all restorations were clinically acceptable. All products received 100% Alpha ratings for gingival adaptation, retention and postoperative sensitivity. Tetric EvoCeram also scored 100% Alpha for colour match, with the other criteria receiving 95%+ Alpha scores. After five years Tetric EvoCeram received higher (or equivalent) scores than the other composites for surface texture, marginal discoloration, gingival adaptation, postoperative sensitivity, colour match and retention.

Conclusion:

There were no statistically significant differences in the performance of the materials tested – whether direct or indirect.

Reference: Cetin et al 2013

Shear bond strengths with Adhese Universal and the Tetric Family of composites: Tetric EvoCeram, Tetric EvoFlow and Tetric EvoCeram Bulk Fill

Study location: **R&D, Ivoclar Vivadent, Schaan, Liechtenstein**

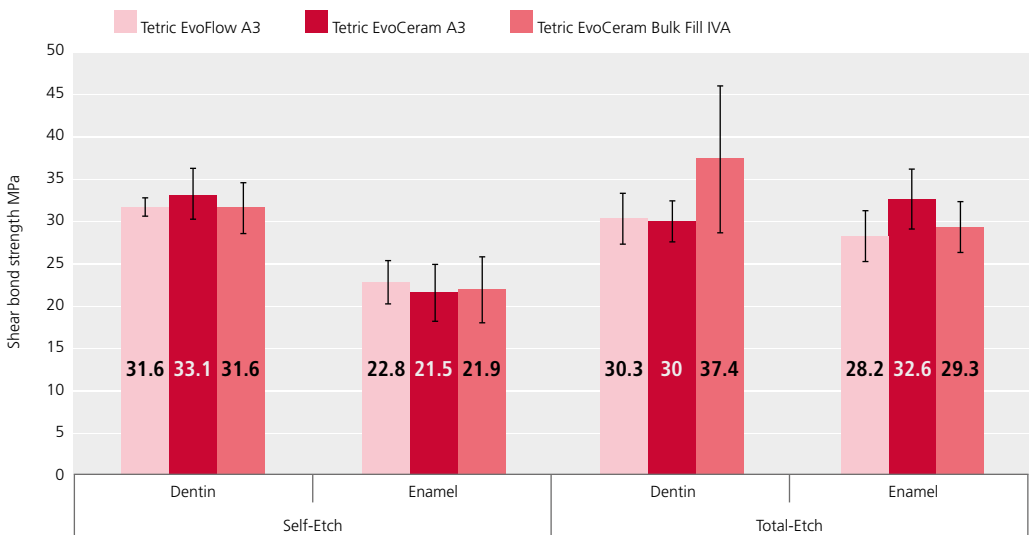
Study time period: **2013**

Study author(s): **R&D Schaan**

Method:

Bond strength tests were carried out with Adhese Universal – a universal adhesive suitable for all etching techniques, together with Tetric EvoCeram, Tetric EvoFlow and Tetric EvoCeram Bulk Fill. The adhesive was applied using both the self-etch technique and the total-etch technique and bond strengths were evaluated on both dentin and enamel. The values shown are the immediate values after bonding.

Results:



Shear bond strengths to Tetric family composites on dentin and enamel using Adhese Universal (self-etch and total-etch techniques)

Summary:

There was no statistically significant difference between the composites for each individual substrate and technique. The bond strength to dentin was comparable; independent of the etching technique and as would be expected, the bond strengths to enamel were somewhat higher in the total-etch group.

Conclusion:

Similar bond strengths were obtained for each of the composites Tetric EvoCeram, Tetric EvoFlow and Tetric EvoCeram Bulk Fill within substrate and etching technique.

Reference: R&D Schaan 2013

In vitro test of the effectiveness of the adhesive Adhese Universal in combination with the composite materials: Tetric EvoCeram and Tetric EvoCeram Bulk Fill in Class V cavities

Study location: **Charité Berlin, Germany**

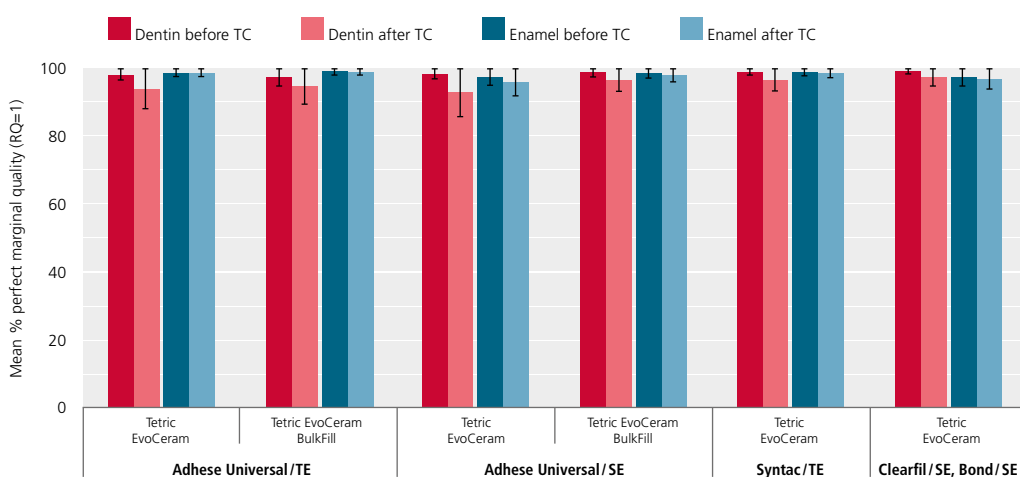
Study time period: **2014**

Study author(s): **Blunck U**

Method:

Eight oval-shaped cavities approx. 4 mm (incisal-apically), 3 mm (mesio-distally) and 1.5 mm deep were prepared in extracted, caries-free human teeth. Adhese Universal (both self-etch and total-etch technique) and either Tetric EvoCeram (2 layers) or Tetric EvoCeram Bulk Fill (1 layer) were applied in the cavities. Syntac (total-etch technique) and Clearfil SE Bond/Kuraray (self-etch technique) were employed as controls in combination with Tetric EvoCeram – establishing six different adhesive/composite groups in total. Silicone impressions were taken before and after thermocycling (2000 cycles between 5°C and 55°C), to evaluate surface quality. Margins were examined using a scanning electron microscope (200x). Marginal quality (RQ), was evaluated according to the scale RQ: 1–4 with 1 representing perfect continuous margins with no marginal gaps observable and 4 representing e.g. large marginal gaps of > 2 µm. The mean values for RQ1 are shown below.

Results:



Mean % perfect marginal quality of Tetric EvoCeram and Tetric EvoCeram Bulk Fill restorations using various adhesives/techniques.

Summary:

There was no statistically significant difference in the quality of the margins in dentin or enamel either before or after thermocycling (TC). There was no statistically significant difference between Adhese Universal or Syntac (in combination with Tetric EvoCeram) when used according to the total-etch technique. There was also no statistically significant difference between Adhese Universal or Clearfil SE Bond (in combination with Tetric EvoCeram) when used according to the self-etch technique.

Conclusion:

The authors conclude, that Adhese Universal proved highly effective in Class V cavities (with both Tetric EvoCeram and Tetric EvoCeram Bulk Fill), when used as a self-etch or total-etch adhesive.

Reference: Blunck 2014

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Tetric EvoCeram[®] Bulk Fill



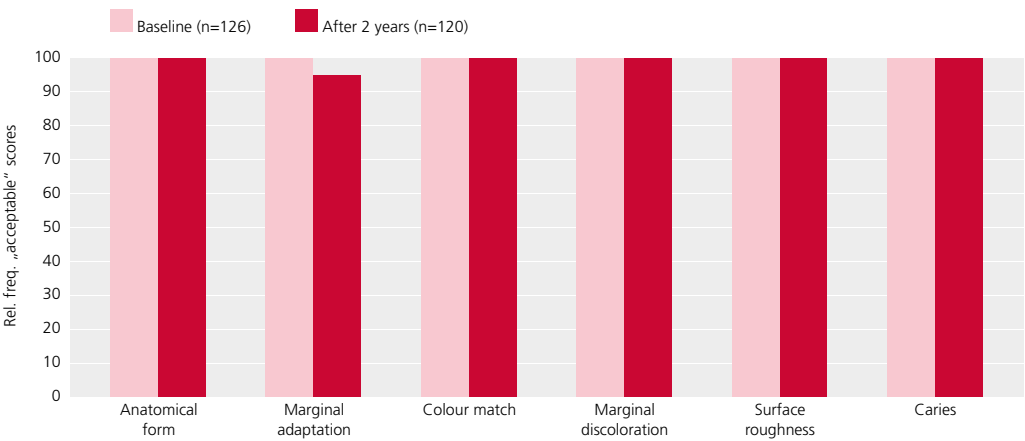
Two year clinical evaluation of Tetric EvoCeram Bulk Fill in Class II cavities – Two year report

Study location: **Umeå University, Sweden**
Study time period: **2 years / 2011 - 2014**
Study author(s): **J. van Dijken**

Method:

Tetric EvoCeram Bulk Fill was evaluated in Class II cavities when placed with 3 different adhesive systems. 126 restorations were placed in 94 patients. Forty in premolars and 86 in molars. Cavities were randomly allotted to bonding with the self-etch adhesives: Adhese One F (n=48) and Xeno V+/Dentsply (n=36) and the total-etch adhesive: Optibond FL/Kerr (n=36). Adhesives were applied according to manufacturer instructions and Tetric EvoCeram Bulk Fill was applied in bulk increments of up to 4 mm and cured for at least 20 s. Restorations were evaluated according to modified USPHS criteria (van Dijken 1986) at baseline and after one and two years. The following characteristics were evaluated and scored as “acceptable” or “unacceptable”: anatomical form, marginal adaptation, colour match, marginal discoloration, surface roughness and secondary caries.

Results:



Relative frequency of “acceptable” scores by characteristic for Tetric EvoCeram Bulk Fill restorations (bonded with various adhesives) at baseline and after 2 years.

Summary:

After one year there were 2 drop-outs involving 3 restorations. All other participants attended both the 1 and 2 year recall. No postoperative sensitivity was reported at any time. Four restorations failed during the first year due to fracture (1), loss of retention (2) or cusp fracture (1) and a further two (n=6) during the second year due to fracture (1) and loss of retention (1). No significant differences were found between the different adhesives used, therefore relative frequencies were calculated for all restorations combined. All of the restorations evaluated, were considered acceptable for all criteria at baseline and also after 2 years with the exception of marginal adaptation where 5% were considered unacceptable due to the six restorations mentioned above.

Conclusion:

No clinical difference was observed between the 3-step total-etch adhesive and the two one-step self-etch adhesives. After 2 years, 100% of the restorations were scored “acceptable” for all criteria other than marginal adaptation.

Reference: van Dijken 2014

Tetric EvoCeram Bulk Fill

Study location: **The Dental Advisor, USA**

Study time period: **2012**

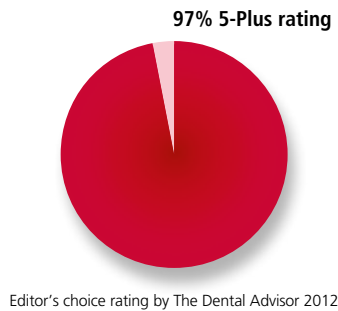
Study author(s): **The Dental Advisor**

Method:

31 consultants placed 746 restorations with Tetric EvoCeram Bulk Fill

Results:

Tetric EvoCeram Bulk Fill was described as having very good handling properties for posterior use, with the 4 mm depth allowing filling of most cavities with one layer – so shortening the application time. It adapted well to cavity walls and was easily “sculptable”. The three shades were adequate for posterior use and their translucency blended naturally with the enamel. In cases of deeply stained dentin it was mentioned that the colour could show through the composite if not blocked out with an opaque liner. Radiopacity was very good.



Summary:

61% of consultants rated Tetric EvoCeram Bulk Fill as better than their current bulk fill product and 32% as equivalent. 84% said they would switch to Tetric EvoCeram Bulk Fill and 94% would recommend it.

Conclusion:

Tetric EvoCeram Bulk Fill achieved a 5-Plus (97%) rating as the Editors' Choice in a Dental Advisor review.

Reference: The Dental Advisor 2012

Tetric EvoCeram Bulk Fill – Two year clinical performance report

Study location: **The Dental Advisor, USA**

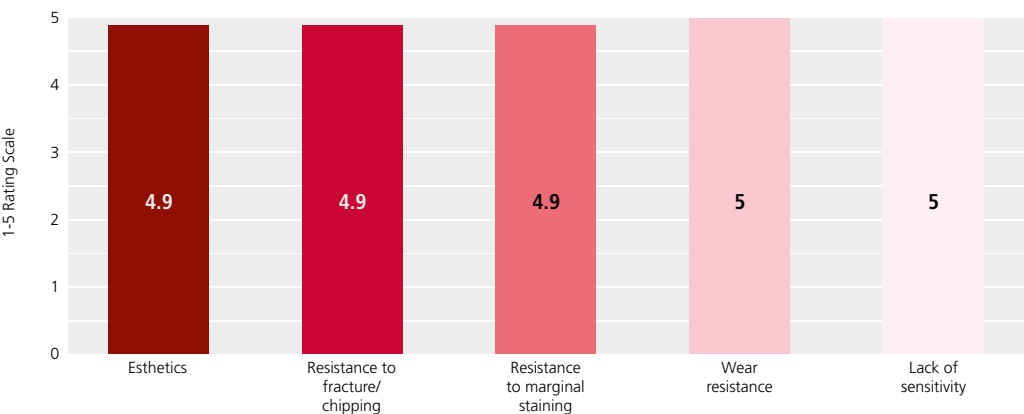
Study time period: **2 years**

Study author(s): **The Dental Advisor**

Method:

Over a two year period, more than 130 Tetric EvoCeram Bulk Fill restorations, involving 1 to 4 surfaces, were placed using self-etching adhesives. After two years, 100 restorations were recalled. Restorations were evaluated regarding: esthetics, resistance to fracture/chipping, resistance to marginal discoloration, wear resistance and lack of postoperative sensitivity. A 1-5 rating scale was used: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent.

Results:



The Dental Advisor rating (1–5) of Tetric EvoCeram Bulk Fill characteristics at two years

Summary:

98% of the recalled restorations exhibited excellent esthetics – with an initial flowable opaquer being recommended for discoloured cavities. Resistance to fracture/chipping was also rated excellent at 4.9. Five restorations were replaced over the two-year period. In one case the root had fractured, necessitating extraction, however this was unrelated to the composite and the other four were very large restorations that subsequently received ceramic crowns. No chipping was noted in any of the other restorations. Four restorations exhibited superficial staining at the cavosurface margin and were successfully re-polished. No wear was observed on any of the restorations or opposing teeth and none of the patients reported any postoperative sensitivity.

Conclusion:

Tetric EvoCeram Bulk Fill performed extremely well. The clinical outcomes of this two-year evaluation of 100 restorations were exceptional. Tetric EvoCeram Bulk Fill received a 99% clinical performance rating.

Reference: The Dental Advisor 2014

A new bulk fill material in clinical use

Study location: **Internal Clinic, R&D, Ivoclar Vivadent, Schaan, Liechtenstein.**

Study time period: **12 months / 2012 – 2013**

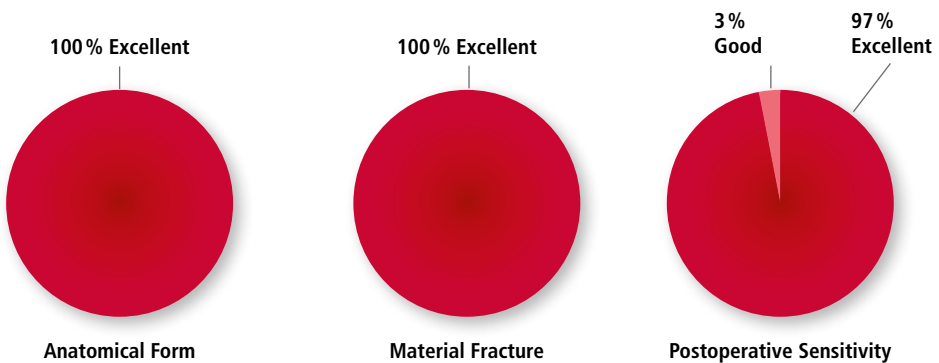
Study author(s): **A. Peschke**

Method:

35 posterior restorations (11 Class I, 24 Class II) were placed by 3 dentists: (dentist 1: n = 12, dentist 2: n = 11, dentist 3: n = 12), together with an experimental etch and rinse adhesive in cavities with an average depth of 4 mm. FDI-criteria were used for evaluation (Hickel et al 2007, 2010), and analysis of the restorative margins was carried out using a (SQUACE) semi-quantitative clinical evaluation method (percentage of total margin). Results were obtained after approximately one week (baseline) and after 12 months.

Results:

There were no postoperative complaints after 1 week in situ and after 12 months, 97% of cases were also rated "Excellent". In terms of esthetics, there was no surface discoloration at any stage (baseline or after one year) and 77% of fillings were considered perfect i.e. "Excellent" with the remaining 23% rated "Good". Polishability was assessed via surface quality, shine and pores and after 12 months, 89% of the fillings were rated either "Excellent" (69%) or "Good" (20%). Overall marginal quality was "Excellent" at both baseline and after 12 months, with over 99% considered "Excellent". There was no change in material fracture or patient satisfaction between baseline and 12 months with both remaining at 100% and 97% "Excellent".



One year ratings (%) of Tetric EvoCeram Bulk Fill restorations by characteristic

Summary:

It was possible to place highly esthetic posterior restorations with Tetric EvoCeram Bulk Fill in increments of up to 4 mm.

Conclusion:

Most criteria were evaluated as "Excellent" at both baseline and after 12 months.

Reference: Peschke 2013

Clinical evaluation of different resin composites in Class II posterior restorations: 1-year results

Study location: **University of Hacettepe, College of Dentistry, Ankara Turkey**

Study time period: **1 year**

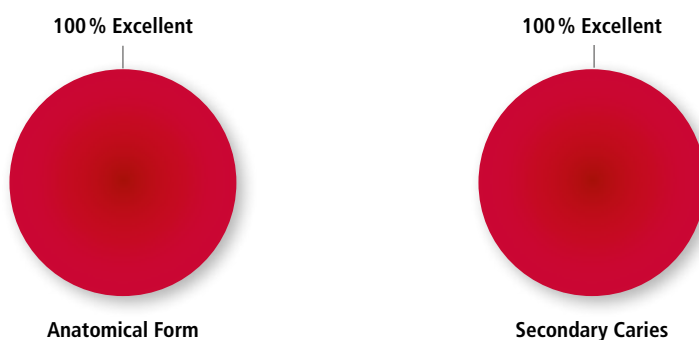
Study author(s): **R. Yazici**

Method:

This split mouth study in 50 patients, compared the 1-year clinical performance of Class II cavities filled with either Tetric EvoCeram Bulk Fill or Filtek Ultimate/3M ESPE. 104 Class II restorations were placed by 2 operators - half with Tetric EvoCeram Bulk Fill/Excite F (n=52) and half with Filtek Ultimate/Adper Single Bond 2/3M ESPE (n=52). Restorations were evaluated at baseline, 6 months and 1 year, according to modified Ryge/USPHS criteria by two "blinded" calibrated examiners. Marginal adaptation, marginal discoloration, colour match, anatomic form, surface texture, secondary caries and postoperative sensitivity were evaluated.

Results:

After 6 months, all 50 patients were recalled. The retention rate was 100% for both products and all criteria were rated "Alpha". One Tetric EvoCeram Bulk Fill restoration exhibited postoperative sensitivity. After 1 year, the patient recall rate was 98% as one patient had moved. All restorations were rated Alpha across all criteria except for two Filtek Ultimate restorations which were rated Bravo on colour match. The same patient as at the six-month-recall, noted mild postoperative sensitivity. There was no secondary caries or loss of anatomical form.



One year ratings (%) of Tetric EvoCeram Bulk Fill restorations by characteristic

Summary:

No statistically significant differences were observed between the two composites ($p > 0.05$).

Conclusion:

Both Tetric EvoCeram Bulk Fill and Filtek Ultimate performed equally well during this 1-year evaluation.

Reference: Yazici 2013

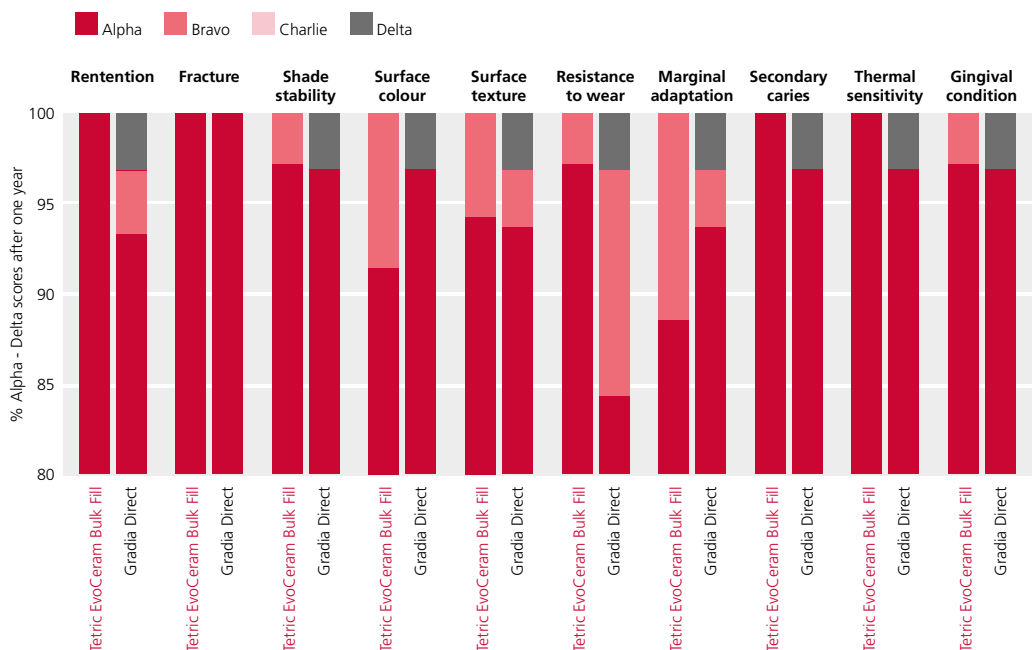
Clinical evaluation of posterior restorations with the composite Tetric EvoCeram Bulk Fill in combination with the total-etch adhesive Excite F

Study location: **University of Toulouse, France**
Study time period: **1 year**
Study author(s): **G. Grégoire**

Method:

To compare the clinical behaviour of Tetric EvoCeram Bulk Fill (with Excite F) and Gradia Direct/GC (with XP Bond/Dentsply), 68 posterior fillings (34 Tetric EvoCeram Bulk Fill and 34 Gradia Direct) were placed in 32 patients by 4 dentists. 4 mm layers were used for Tetric EvoCeram Bulk Fill and 2 mm layers for Gradia Direct. All restorations were cured for 20 s using Bluephase (1200 mW/cm²) and polished with OptraPol. The clinical evaluation (modified USPHS) was carried out at baseline, after 6 months and 1 year by the operator and an independent evaluator.

Results:



One year clinical evaluation of Tetric EvoCeram Bulk Fill and Gradia Direct. Percentage "Alpha-Delta" ratings by characteristic

Summary:

Tetric EvoCeram Bulk Fill exhibited perfect clinical behaviour at baseline, with all evaluated criteria rated as Alpha. After 1 year (as shown in the graph), Tetric EvoCeram Bulk Fill exhibited 100% Alpha scores for the criteria: retention, fracture, secondary caries and thermal-sensitivity. Gradia Direct had 100% Alpha scores for fractures only, with all other criteria exhibiting 3.2% Delta scores. The esthetics of Tetric EvoCeram Bulk Fill were notable with over 90% rated Alpha for shade stability and surface colour.

Conclusion:

Tetric EvoCeram Bulk Fill exhibited excellent clinical behaviour after one year with no score below Bravo. The scores for Tetric EvoCeram Bulk Fill exceeded those of Gradia Direct for all criteria except fractures.

Reference: Grégoire 2013

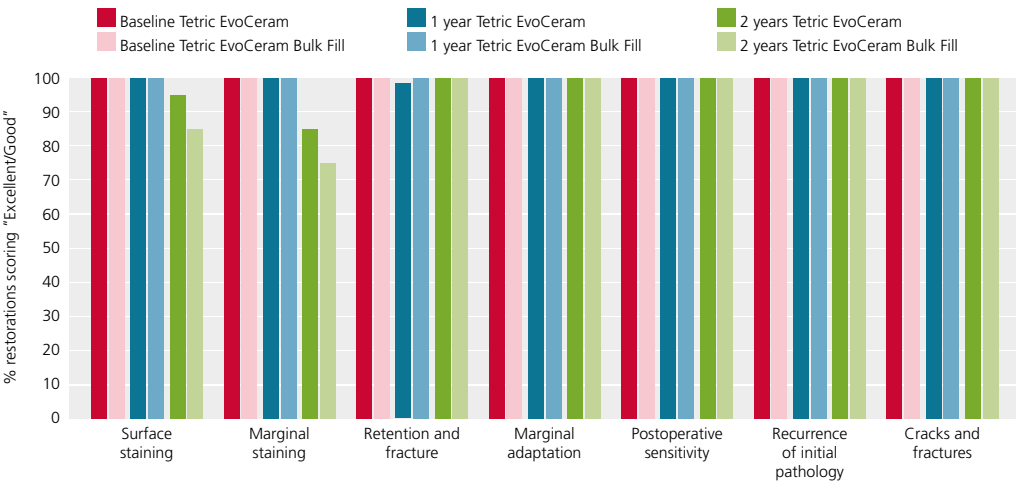
Clinical evaluation of Tetric EvoCeram and Tetric EvoCeram Bulk Fill with Excite in a split mouth study

Study location: **Universidad Complutense de Madrid, Spain**
Study time period: **2 years / 2011 - 2014**
Study author(s): **A. Saralegui**

Method:

23 patients were included in this study, with each patient receiving one Tetric EvoCeram (Group 1) and one Tetric EvoCeram Bulk Fill (Group 2) restoration. All restorations were bonded with Excite and evaluated by a different operator to the treating-clinician. The following clinical criteria were evaluated: Surface staining, marginal staining, retention & fracture, marginal adaptation, postoperative sensitivity, recurrence of initial pathology, cracks & fractures and proximal contact points. The criteria were evaluated using Hicel/FDI criteria with scores from 1 to 5. 1 = clinically excellent, 2 = clinically good, 3 = clinically sufficient, 4 = clinically unsatisfactory and 5 = clinically poor. Recalls took place at baseline after 6 months, 1 year and 2 years.

Results:



Percentage Tetric EvoCeram and Tetric EvoCeram Bulk Fill restorations rated "Excellent/Good" by characteristic – at baseline, 1 year and 2 years

Summary:

After 1 and 2 years, 21 and 20 patients respectively were available for recall. At baseline all criteria achieved top scores (Score = 1) apart from postoperative sensitivity in which two Tetric EvoCeram teeth and three Tetric EvoCeram Bulk Fill teeth scored 2. The graph compiles the percentages of teeth scoring 1 or 2 i.e. clinically good or better. At baseline and after one year, 100% achieved this for all criteria. After 2 years this was also maintained for retention & fracture, marginal adaptation, postoperative sensitivity, recurrence of initial pathology and cracks & fractures. Surface staining and marginal staining both deteriorated slightly after two years. However 95% and 85% of the Tetric EvoCeram/Tetric EvoCeram Bulk Fill restorations respectively still received a score of 1 or 2 for surface staining and 85% and 75% for marginal staining.

Conclusion:

Tetric EvoCeram Bulk Fill and Tetric EvoCeram performed very well two years after placement for all criteria, achieving scores of good or excellent for most criteria. There were no scores lower than 3 for either product. The authors note the good manipulation properties of Tetric EvoCeram Bulk Fill and consider it comparable in its ease of use to Tetric EvoCeram.

Reference: Saralegui 2014

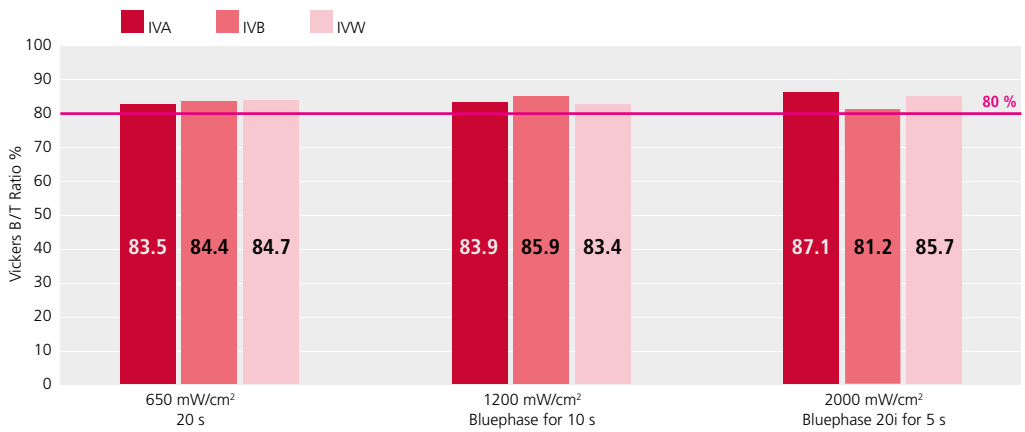
Bottom/Top Vickers Hardness ratios of Tetric EvoCeram Bulk Fill shades

Study location: **R&D, Ivoclar Vivadent, Schaan, Liechtenstein**
Study time period: **2011**
Study author(s): **R&D Schaan**

Method:

Samples of each of the three Tetric EvoCeram Bulk Fill shades were made and the Vickers Hardness was measured at the top and at a depth of 4 mm. The values measured at the top were set to 100% and the values measured at 4 mm were expressed as a percentage of this value. Various light intensities were employed using different curing lights and the curing times were adjusted accordingly to ensure a similar light output in each case.

Results:



Vickers hardness as % of surface hardness (at 4 mm depth) for the 3 shades of Tetric EvoCeram Bulk Fill – with different polymerisation protocols

Summary:

Professor David Watts of the University of Manchester, UK posed that an acceptable curing depth is achieved when the bottom hardness corresponds to at least 80% of the surface hardness (Watts et al 1984). The recommended maximum increment thickness for Tetric EvoCeram Bulk Fill is 4 mm. At a 4 mm depth, the 80% level was exceeded under all experimental circumstances.

Conclusion:

All shades achieved an adequate level of cure at a depth of 4 mm with various curing lights.

Reference: R&D Schaan 2011

Depth of cure of Tetric EvoCeram Bulk Fill cured with Bluephase G2 and Bluephase Style in comparison to other composites

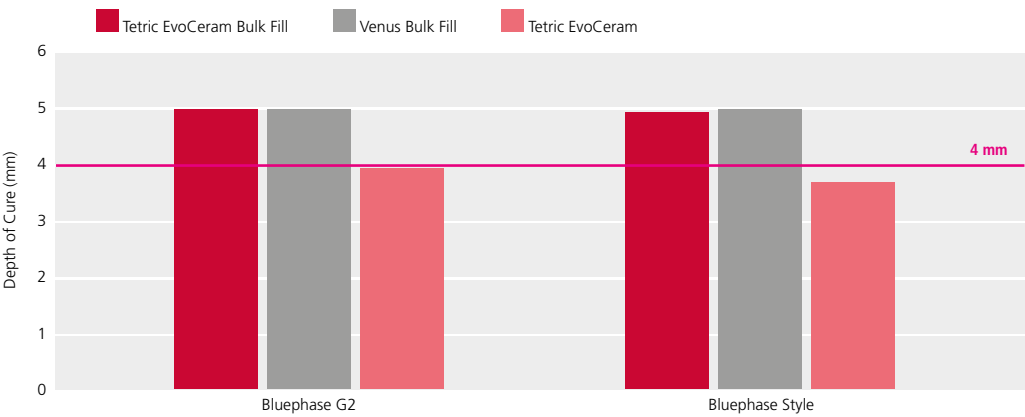
Study location: **Universitätsklinikum Jena, Germany**
Study time period: **2012**
Study author(s): **A. Rzanny, M. Fachet**

Method:

Depth of cure was measured for the composites Tetric EvoCeram, Tetric EvoCeram Bulk Fill and Venus Bulk Fill/Heraeus Kulzer, according to the ISO standard 4049. Specimens with a diameter of 6 mm and a height of 10 mm were fabricated and cured for 10 s with a Bluephase G2 or a Bluephase Style curing lamp. The length of the cured material was measured immediately after polymerisation and the value was divided by 2.

Results:

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



Depth of cure of Tetric EvoCeram Bulk Fill, Tetric EvoCeram and Venus Bulk Fill when cured with Bluephase G2 and Bluephase Style for 10 seconds

Summary:

Using the EN ISO 4049 method for establishing depth of cure, Tetric EvoCeram Bulk Fill and Tetric EvoCeram both exceeded their maximum stipulated layer thicknesses.

Conclusion:

Both Tetric EvoCeram Bulk Fill and Venus Bulk Fill exceeded their stipulated curing depth. Both Bluephase G2 and Bluephase Style are equally suitable for polymerising the composites investigated.

Reference: Rzanny et al 2012

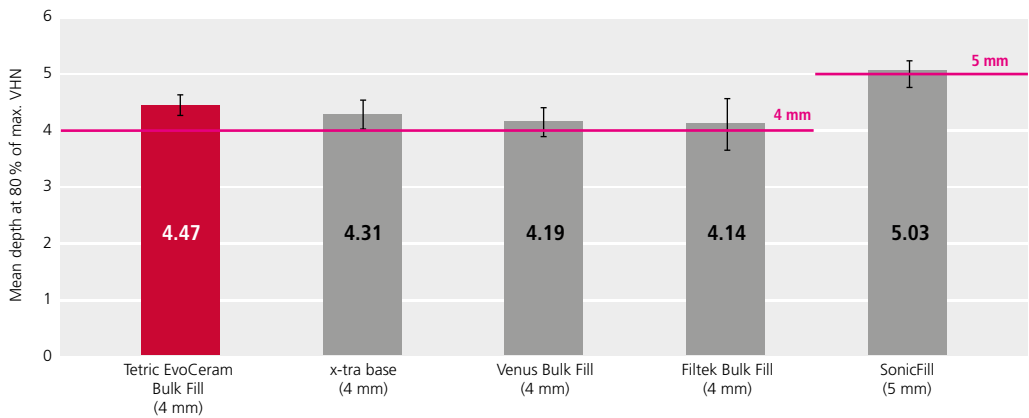
Post-cure depth of cure of bulk fill dental resin-composites

Study location: **University of Manchester, Manchester, UK**
Study time period: **2014**
Study author(s): **A. Alrahlah, N. Silikas, D. Watts**

Method:

Average depth of cure was calculated for 5 different bulk fill composites (Tetric EvoCeram Bulk Fill, x-tra base/Voco, Venus Bulk Fill/Heraeus Kulzer, Filtek Bulk Fill/3M Espe, SonicFill/Kerr) by calculating the mean (n=3 per material) depth at which the Vickers hardness was 80% of the maximum Vickers hardness. Composites were cured in 15 mm long stainless steel moulds for 20 s and stored for 24 hours at 37 °C. Vickers profiles were made at 0.3 mm intervals throughout the material.

Results:



Average depth at 80% of maximum Vickers hardness for various bulk fill composites (max. recommended increment thickness shown in brackets)

Summary:

The mean depth of cure was 4.47 mm for Tetric EvoCeram Bulk Fill, exceeding the maximum increment thickness of 4 mm.

Conclusion:

All of the bulk fill composites tested, exceeded the depth of cure stipulated by the respective manufacturer. Tetric EvoCeram Bulk Fill and Sonic Fill demonstrated the greatest depth of cure among the composites examined.

Reference: Alrahlah et al 2014

Light transmittance and micro-mechanical properties of bulk fill vs. conventional resin based composites

Study location: **Ludwig-Maximilians-University Munich, Germany**

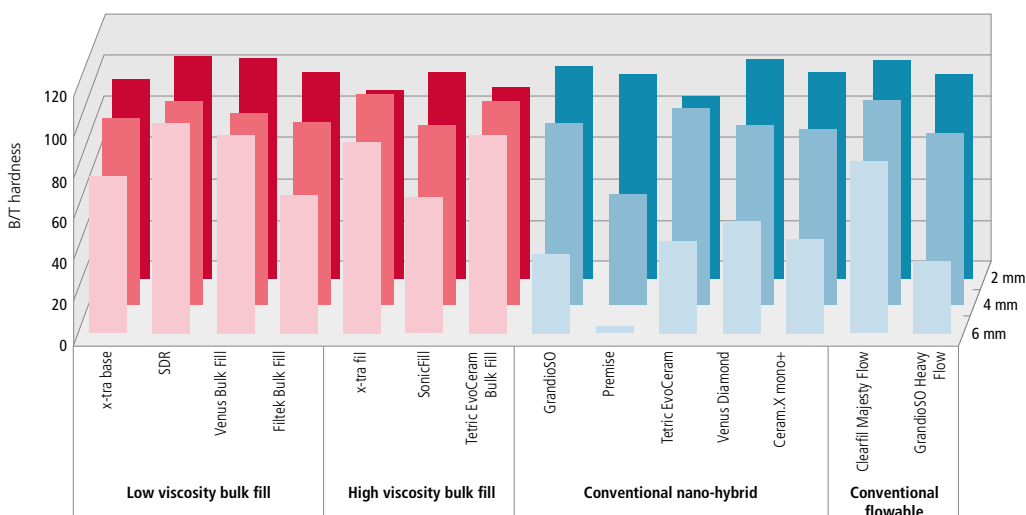
Study time period: **2014**

Study author(s): **S. Bucuta S, N. Ilie**

Method:

7 bulk fill (flowable and sculptable: x-tra-base/Voco, SDR/Dentsply, Venus Bulk Fill/Heraeus Kulzer, Filtek Bulk Fill/3M Espe, x-tra fil/Voco, SonicFill/Kerr and Tetric EvoCeram Bulk Fill), **5 conventional** (GrandioSO/Voco, Premise/Kerr, Tetric EvoCeram, Venus Diamond/Heraeus Kulzer and Ceram.X mono+/Dentsply) and **2 flowable conventional composites** (Clearfil Majesty Flow/Kuraray, GrandioSO Heavy Flow/Voco) in shade "A3" were tested. Specimens were placed in moulds and cured from the top for 20 s. Transmitted irradiance was measured from the bottom of the specimens via spectrometer. Vickers Hardness was measured using a microhardness indenter. The surface hardness was set at 100% and bottom/top (B/T) hardness ratios were also calculated.

Results:



Bottom/Top hardness ratios at 2, 4 and 6 mm for various bulk fill, conventional and flowable composites

Summary:

Bulk fill composites (shown in red on the left) showed fairly consistent Vickers hardness values and thus high and relatively consistent B/T hardness ratios - independent of layer thickness. In contrast conventional composites (shown in blue on the right) showed very divergent B/T ratios due to larger differences in the Vickers hardness in comparison to the surface i.e. the 6 mm ratios were far lower than the 4 and 2 mm ratios. All materials achieved the $\geq 80\%$ B/T hardness when cured in 2 mm increments for conventional composites and 4 mm increments for bulk fill composites. Tetric EvoCeram Bulk Fill, Venus Bulk Fill, SDR and x-tra fil even exceeded an 80% bottom/top hardness ratio in 6 mm increments.

Conclusion:

There was a clear difference between the B/T hardness ratios at increasing depth for conventional and bulk fill composites. Tetric EvoCeram Bulk Fill achieved $\geq 80\%$ hardness ratio at all increment depths measured.

Reference: Bucuta et al 2014

Comparative shrinkage measurements of different dental composites

Study location: **Fraunhofer-Institut für Werkstoffmechanik, Freiburg, Germany**

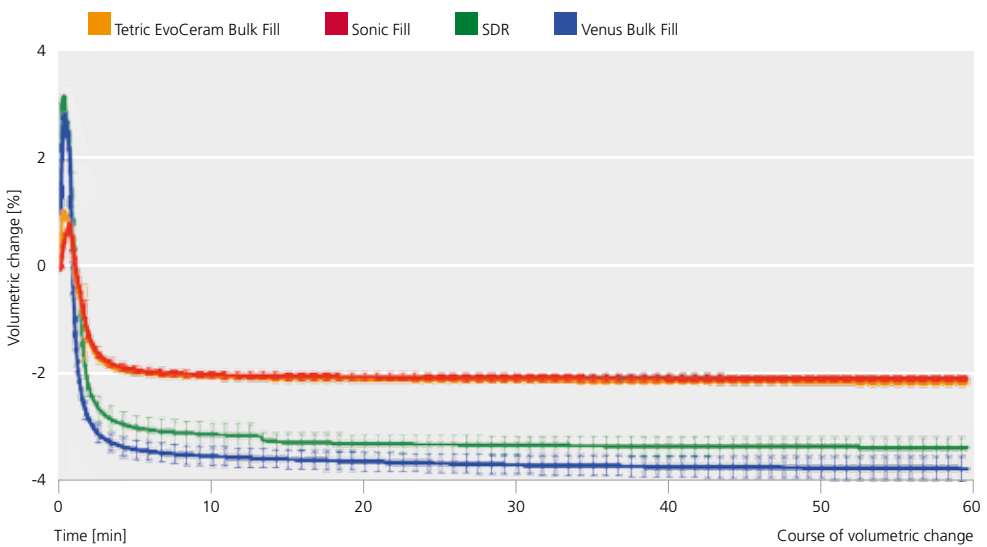
Study time period: **2011**

Study author(s): **C. Koplin, R. Jaeger**

Method:

Polymerisation shrinkage was tested in four bulk fill products (Tetric EvoCeram Bulk Fill, SDR/Dentsply, Venus Bulk Fill/Heraeus Kulzer and SonicFill/Kerr) using the buoyancy (Archimedes) technique. Free-floating samples were polymerised whilst floating in silicone oil (of known density). Five measurements were carried out for each material and each measurement was executed over a 60 minute period at room temperature.

Results:



Course of volumetric change over 60 minutes in various bulk fill composites

Summary:

At the beginning of the polymerisation process, an expansion in volume is observed. This is due to the rise in temperature at the onset of the exothermic polymerisation reaction as well as the exposure to light during photoactivation. The exponential decrease in volume comes to a virtual standstill after 10 minutes and after 60 minutes the final mean shrinkage values were determined: Tetric EvoCeram Bulk Fill: 2.13%, SonicFill: 2.06%, Venus Bulk Fill: 3.7% and SDR: 3.3%.

Conclusion:

The two sculptable composite materials Tetric EvoCeram Bulk Fill and SonicFill exhibited lower shrinkage than the two flowable bulk fill materials Venus Bulk Fill and SDR.

Reference: Koplin et al 2011

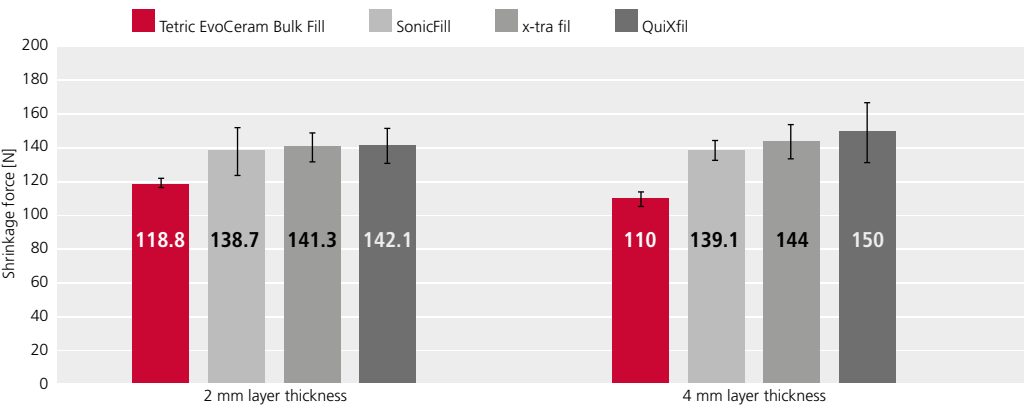
Shrinkage and contraction force of bulk filling and microhybrid composites

Study location: **R&D, Ivoclar Vivadent, Schaan, Liechtenstein**
Study time period: **2012**
Study author(s): **K. Vogel, V. Rheinberger**

Method:

Polymerisation contraction force was measured using a Bioman shrinkage stress instrument. (D. Watts, Manchester UK). Composite specimens (Tetric EvoCeram Bulk Fill, SonicFill/ Kerr, x-tra fil/Voco and QuiXfil/Dentsply) with a 10 mm diameter and a height of 0.8, 2 or 4 mm were placed between and adhered to a sandblasted metal rod and a silanated glass plate. Specimens (n=3 per composite) were cured from below using a Bluephase G2 HIP (1200 mW/cm²) for 10 s. Contraction forces were recorded continuously for 30 minutes.

Results:



Shrinkage force of various sculptable bulk fill materials measured in 2 mm and 4 mm layer thicknesses

Summary:

Within composites - there was little difference in the contraction/shrinkage stress for 2 mm or 4 mm increments. A 4 mm increment of Tetric EvoCeram Bulk Fill showed even less contraction force than 2 mm of the other products.

Conclusion:

Tetric EvoCeram Bulk Fill exhibited the lowest contraction force of all the bulk fill materials in both 2 mm and 4 mm increments.

Reference: Vogel et al 2012

Mean surface gloss and roughness of various bulk fill composites in relation to polishing time

Study location: **Preclinic, R&D, Ivoclar Vivadent, Schaan, Liechtenstein**

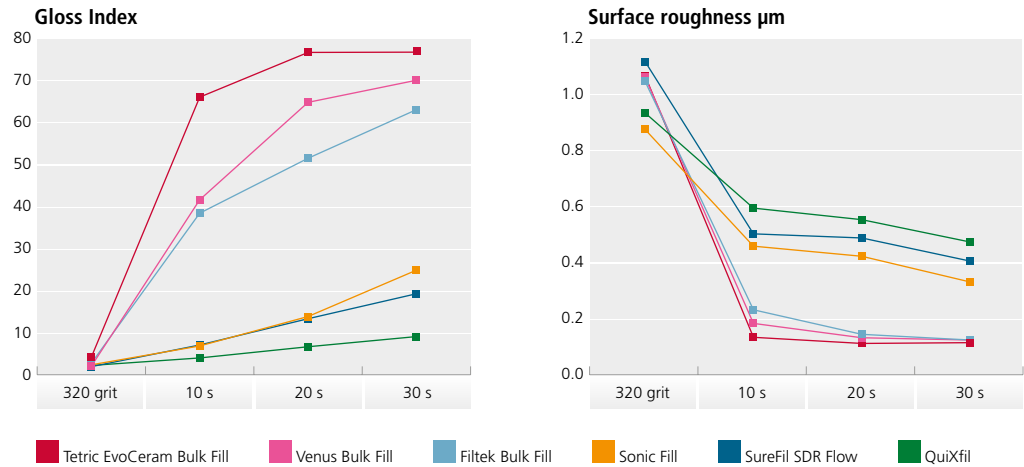
Study time period: **2011**

Study author(s): **S. Heintze**

Method:

Eight specimens each of six different bulk fill materials (Tetric EvoCeram Bulk Fill, Venus Bulk Fill/ Heraeus Kulzer, Filtek Bulk Fill/3M Espe, SonicFill/Kerr, SureFil SDR Flow/Dentsply, QuiXfil/Dentsply) were prepared according to manufacturer instructions. Specimens were roughened with sand paper (320 grit) to achieve a defined initial surface roughness, then stored in a dry area at 37 °C for 24 hours – whereupon gloss was measured with a Novo-Curve Glossmeter and surface roughness was determined with an FRT MicroProf measuring device. Specimens were then polished using a single-step OptraPol polisher under water cooling for 30 s. Surface gloss and roughness were measured at 10 s intervals.

Results:



Mean surface gloss and roughness of various bulk fill materials after polishing with OptraPol

After 10 seconds polishing, Tetric EvoCeram Bulk Fill exhibited the highest surface gloss and the lowest surface roughness of all the materials tested.

Summary:

The higher the gloss and lower the surface roughness, the better the polishability of a material. A mean surface roughness < 0.1 µm indicates excellent polishability, < 0.2 µm suggests good polishability, a value between 0.2–0.4 µm corresponds to a medium polishability and > 0.4 µm means poor polishability. Tetric EvoCeram Bulk Fill exhibited excellent polishability and after 30 seconds polishing there was no significant difference in surface roughness between Tetric EvoCeram Bulk Fill, Venus Bulk Fill and Filtek Bulk Fill.

Conclusion:

After 10 seconds polishing Tetric EvoCeram Bulk Fill exhibited the highest surface gloss and the lowest surface roughness of all the materials tested. Tetric EvoCeram Bulk Fill samples exhibited a statistically significant higher surface gloss than the other materials at all stages of polishing and also exhibited low surface roughness.

Reference: R&D Schaan 2011

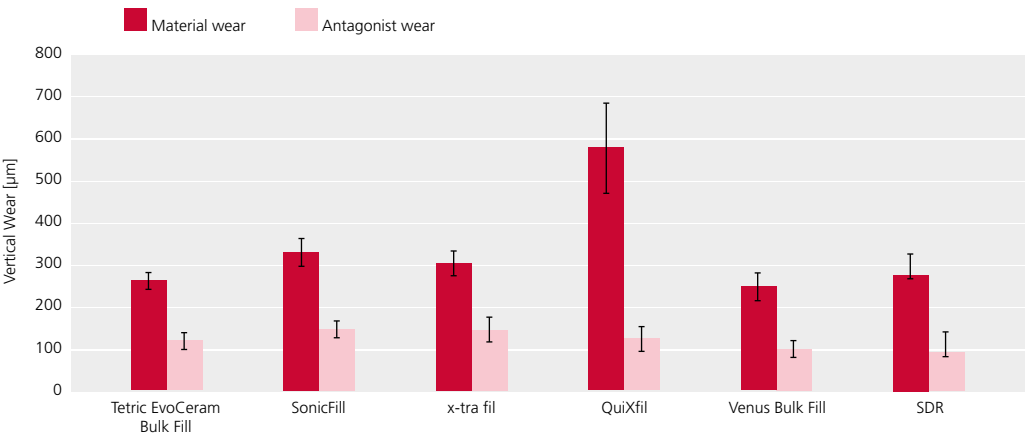
Mean vertical wear of restorative materials and their antagonists

Study location: **Preclinic, R&D, Ivoclar Vivadent, Schaan, Liechtenstein**
Study time period: **2011**
Study author(s): **S. Heintze**

Method:

A Willytec chewing simulator was used to measure the wear resistance of Tetric EvoCeram Bulk Fill compared to the restorative materials: SonicFill/Kerr, x-tra fil/Voco, QuiXfil/Dentsply, Venus Bulk Fill/Heraeus Kulzer and SDR/Dentsply. Standardised ceramic antagonists made of IPS Empress were employed and plane test samples were subjected to 120,000 masticatory cycles, with a force of 50 N and a sliding movement of 0.7 mm. The vertical substance loss was then 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.

Results:



Mean vertical wear of various composites and their IPS Empress antagonists

Summary:

Tetric EvoCeram Bulk Fill, SDR and Venus Bulk Fill exhibited comparable medium low wear, whereas QuiXfil and SonicFill showed significantly higher wear. With regard to antagonist wear, there was less variation but significantly higher wear was recorded for SonicFill and x-tra fil test samples.

Conclusion:

The results regarding wear for Tetric EvoCeram Bulk Fill were largely comparable to other bulk fill composites.

Reference: R&D Schaan 2011

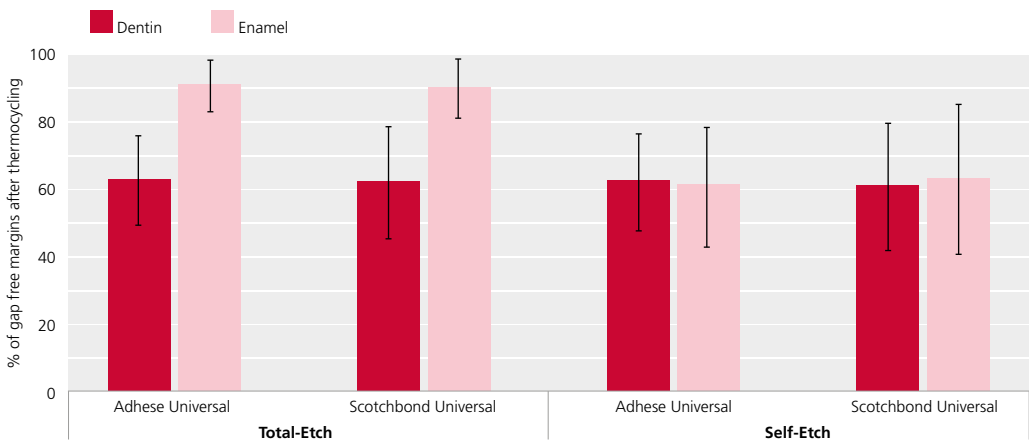
Marginal quality in dentin and enamel of Tetric EvoCeram Bulk Fill restorations placed with universal adhesives

Study location: **University of Marburg, Germany**
Study time period: **2014**
Study author(s): **R. Frankenberger**

Method:

32 MOD cavities with one proximal box beneath the cement-enamel junction were prepared in extracted human molars. Restorations were placed with Tetric EvoCeram Bulk Fill and either Adhese Universal or Scotchbond Universal/3M Espe. Both self-etch and total-etch techniques were used. Marginal gaps in the enamel were analysed via SEM of epoxy-resin replicas, before and after thermocycling (100,000 x 50N, 2500 cycles between 5°C and 55°C). After thermo-mechanical loading, specimens were cut longitudinally to investigate the internal dentin adaptation under SEM (200x magnification). Results were analysed with Kruskal-Wallis and Mann-Whitney U-tests ($p < 0.05$).

Results:



Percentage gap-free margins after thermocycling - in Tetric EvoCeram Bulk Fill restorations bonded with Adhese Universal or Scotchbond Universal.

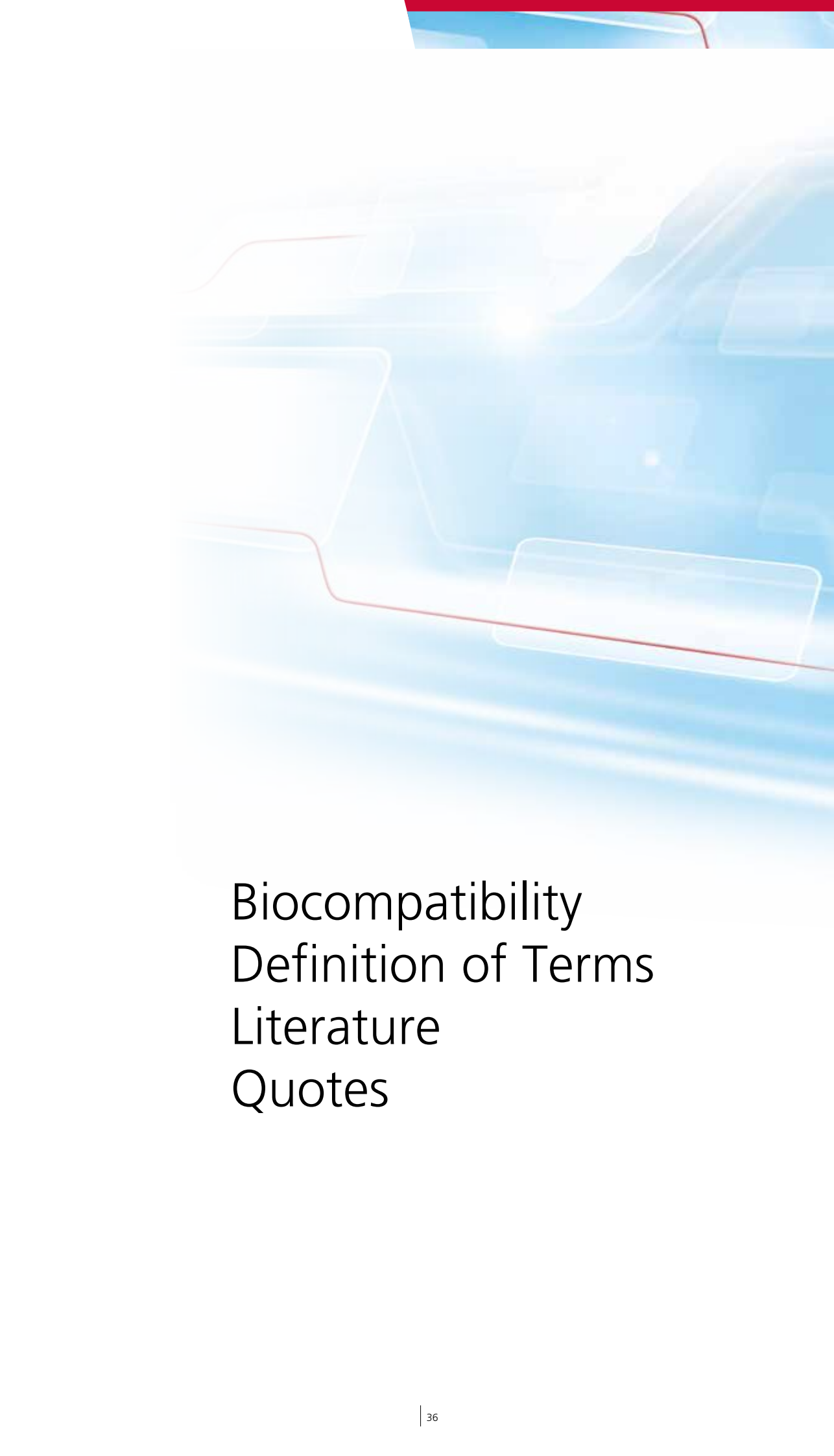
Summary:

Pre-thermocycling the percentages of margin with perfect integrity were high in both enamel and dentin for both adhesives and techniques. After thermocycling (see graph) there was no significant difference between the etching techniques or adhesives in dentin. In enamel, the percentage of gap free margins was higher in the total-etch group than the self-etch group, but the differences were not significant.

Conclusion:

When compared to adhesives and filling composites tested previously under equal conditions, Adhese Universal (plus Tetric EvoCeram Bulk Fill) performs very well using both the total-etch and self-etch techniques on dentin and enamel.

Reference: Frankenberger 2014



Biocompatibility
Definition of Terms
Literature
Quotes

Biocompatibility

Biocompatibility can be defined as the ability of a substance/material to be in contact with a living system without producing an adverse effect. Tests indicate the reactivity or tolerance of cells (often mouse fibroblasts) to soluble compounds of a material. Tests may include cytotoxicity, mutagenicity, irritation and sensitivity.

In the development of new products - to minimise any biocompatibility risks from the outset, Ivoclar Vivadent strives to use well-established raw materials that have already proven safe *in vivo*.

The composition of Tetric EvoCeram was based on its predecessor Tetric Ceram and Tetric EvoCeram Bulk Fill is based on that of Tetric EvoCeram. The biocompatibility of Tetric EvoCeram and Tetric EvoCeram Bulk Fill was assessed according to the International Standards: EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and EN ISO 7405: Dentistry – Evaluation of biocompatibility of medical devices used in dentistry.

Cytotoxicity:

RCC – CCR Report No. 814702. Meurer K, 2004: Cytotoxicity assay *in vitro*.

Harlan Report No.1446301. Heppenheimer A, 2011: Cytotoxicity assay *in vitro*: Evaluation of materials for medical devices (XTT-Test).

RCC – CCR Report No.1191102. Heppenheimer A, 2008: Cytotoxicity assay *in vitro*: Evaluation of test items in the XTT Test.

Mutagenicity:

RCC – CCR Report No. 814705. Sokolowski A, 2004: Salmonella typhimurium and Escherichia coli reverse mutation assay.

Harlan Report CCR Study No.1446302. Sokolowski A, 2011: Salmonella typhimurium and Escherichia coli reverse mutation assay.

RCC – CCR Report No. 1120103. Meurer K, 2007: Single cell gel electrophoresis (Comet Assay) in Chinese hamster V79 cells

RCC – CCR Report No.1120104. Sokolowski A, 2007: Salmonella typhimurium and Escherichia coli reverse mutation assay.

RCC – CCR Report No. 1191101. Hornarvar N, 2008: Micronucleus assay in bone marrow cells of the mouse.

Sensitivity:

Like virtually all light-cured dental materials, the family of Tetric EvoCeram composites contains methacrylates and dimethacrylates. These materials (notably in their uncured state), may cause sensitisation, which can lead to allergic reactions, such as contact dermatitis. Allergic reactions are very rare in patients but occur more frequently among dental staff who handle uncured material on a daily basis. Such reactions can be minimised or avoided by clean working conditions and avoiding skin contact with uncured material. It should be noted however that commercially available medical gloves do not provide effective protection against the sensitising effects of methacrylates. Neither Tetric EvoCeram nor Tetric EvoCeram Bulk Fill should be used in patients known to be allergic to any of their constituents.

Conclusion:

The results of biocompatibility tests with Tetric EvoCeram and Tetric EvoCeram Bulk Fill (or other products comprising the same monomer composition) do not indicate any risk for patients, users or third parties when the products are used according to the instructions for use. On the basis of the data available, including ten years of clinical experience with Tetric EvoCeram, it can be concluded that the Tetric EvoCeram composite family of products poses no health hazard if used correctly and the benefits of their use outweigh any residual risk.

Definition of terms

Bulk Fill

Dental composites denoted as bulk fill are restorative materials that can be applied in thick increments i.e. typically in increments of 4 mm or more, as opposed to standard composites which are traditionally applied in up to 2 mm increments. Bulk Fill materials are available in sculptable and flowable form depending on the manufacturer. Sculptable bulk fill composites can be applied in one layer, flowable composites require the additional application of a sculptable composite in order to create the natural tooth topography.

Clinical Evaluation Techniques for Restorations

Cvar and Ryge/USPHS Criteria (Cvar & Ryge 1971 and 2005)

Cvar and Ryge developed their much used measurement scale over 40 years ago. This method of evaluation is interchangeably referred to as Cvar & Ryge criteria, Ryge criteria or USPHS criteria. The criteria were drawn up at a time when the longevity of direct restorative materials other than amalgam was limited, thus many modifications of these criteria have been made by various authors in an attempt to make the criteria more discriminating for modern restorative materials. These are referred to as **modified Ryge** or **modified USPHS criteria**. Virtually every modification is slightly different (Hickel et al, 2007).

The criteria use the Alpha, Bravo, Charlie, Delta evaluation scale. These scores have different meanings depending on the criteria being assessed however in general:
Alpha = excellent/optimal, Bravo = acceptable,
Charlie = unacceptable/insufficient and Delta = needs replacing.

Hickel/FDI Criteria (Hickel et al, 2007)

As part of the FDI World Dental Federation Science Committee, Hickel et al published a paper in 2007 outlining a proposal for a more modern clinical evaluation of composite restorations. They present evaluation criteria related to the original Ryge criteria. These are evaluated as follows: Score 1 = Excellent, Score 2 = Very good but not ideal, Score 3 = Sufficient with minor shortcomings, Score 4 = Unacceptable but repairable, Score 5 = Unacceptable and needs replacing. Hickel et al compare their scoring system with Cvar and Ryge as follows:

Cvar & Ryge	Hickel/FDI
Alpha	Scores 1 & 2
Bravo	Score 3
Charlie	Score 4
Delta	Score 5

Mechanical properties	In materials science, there are numerous test methods to determine the mechanical properties of materials. The object of mechanical testing of dental materials is to make estimates about the clinical efficacy of a material. However, the standard test methods most frequently test isolated stress conditions, the effects on a material are however much more complex in clinical reality. Nevertheless materials science examinations in the laboratory do permit the comparison of different materials when tested in exactly the same way.
Depth of cure	Refers to how deep a composite material has been polymerised. 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.
Hardness	The hardness of a material is the resistance of a material to penetration by another body. Various methods can determine hardness, such as Vickers, Knoop, Brinell and Rockwell. Hardness is often expressed as a percentage of the surface hardness which is considered 100%. It is generally accepted that an acceptable curing depth is achieved if the bottom hardness corresponds to at least 80% of the surface hardness.
Vickers Hardness	This test utilises a diamond pyramid shaped indenter that is ground in the form of a squared pyramid with an angle of 136° between faces.
Knoop Hardness	This test utilises a diamond elongated pyramid shaped indenter that is ground to an elongated pyramidal form that produces a diamond shaped indentation.
Bottom/Top Hardness Ratio	<p>The bottom/top hardness ratio (B/T Hardness Ratio) is based on the premise that a composite is considered sufficiently cured if the bottom hardness (or the hardness at whatever depth you are investigating corresponds to at least 80% of the surface hardness (100%).</p> <p>i.e. Adequate depth of cure if:</p> <p>Bottom Hardness/Top Hardness x 100 ≥ 80</p>

Polymerisation Shrinkage

Polymerisation shrinkage refers to the shrinking of resin based composite restorations during and after polymerisation. Due to the creation of chemical bonds between the monomers, less space is required between the molecules – resulting in reduced volume i.e. shrinkage. Shrinkage is considered a potential problem as it could lead to poor marginal seal, marginal staining or caries.

Volumetric shrinkage

Refers to the reduction in actual volume of the placed restoration after polymerisation.

Shrinkage stress

Refers to the stress on the tooth or cavity walls due to the volumetric shrinkage. As composites are fixed to the tooth structure with adhesive, they cannot shrink freely during the shrinkage process, which puts a strain on the adhesive bond.

Modulus of elasticity

Refers to the tendency to be deformed elastically. A high modulus of elasticity denotes inelasticity and a low modulus of elasticity denotes higher elasticity. During curing, the modulus increases i.e. the material becomes stiffer.

Studies

Studies are conducted to forecast or examine the behaviour of materials when used for the intended application. Most frequently the aspects of functionality, reliability and safety, compatibility or user-friendliness are of interest.

***In vitro* studies**

in vitro means “in glass” i.e. these are examinations conducted in a laboratory. Many materials science or toxicological tests are carried out *in vitro*, since they cannot be conducted on human beings for practical or ethical reasons. Moreover *in vitro* studies have the advantage that researchers can work under standardised conditions plus they are often quicker and less expensive than *in vivo* studies

***In vivo* studies**

in vivo means “in the living object” i.e. clinical studies on human beings. The advantage is that they are conducted under real conditions. They are however complex due to a wealth of possible influencing factors. They require exact planning, systematic methods and statistically correct evaluation. Randomised controlled studies are considered the gold standard.

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Quotes

Dr John W. Farah – The Dental Advisor

What changes in composites do you feel have most dramatically impacted dentistry over the past 30 years?

„Modern composites definitely have better handling, resulting in easier placement. I prefer composites that are somewhat condensable - more viscous and more highly filled – resulting in easier contouring and development of anatomy. I want a composite that is easy to shape and will maintain its form but not drag.

Good examples are Tetric EvoCeram (Ivoclar Vivadent) and Aura [SDI (North America) Inc.]. Modern composites also have better wear characteristics and excellent shade stability. I just observed a Tetric EvoCeram composite where there was no detectable wear and the shade was perfect after 10 years. Because of the very small size of filler particles, modern composites polish well and retain their gloss over time too. The strength properties are outstanding; it is rare for a clinician to see an actual fracture of a composite.“

Excerpt from The Dental Advisor 2014, April, Vol. 31, No. 03

Prof. Dr Jürgen Manhart



“I have used Tetric EvoCeram for a decade.
My patients’ fillings look great, even years after placement.”

A handwritten signature in black ink, which appears to read 'J. Manhart'.

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"I believe that Tetric EvoCeram Bulk Fill is a very good composite material with excellent handling properties. Furthermore, it simplifies and expedites the layering procedure. You can almost say that, once you have worked with Tetric EvoCeram Bulk Fill, you no longer want to work with conventional composites."

Dr Eduardo Mahn



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"I have used Tetric EvoCeram ever since it was launched. It is very reassuring to see that the quality of the restorations continues to be outstanding, even after a number of years. My experiences have been excellent not only with Tetric EvoCeram, but also with its predecessor, Tetric Ceram. Therefore, I expect similar performance using the further developed Tetric EvoCeram Bulk Fill."

Dr Arnd Peschke



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"The systematic review of 10-year-old posterior restorations made of Tetric EvoCeram yielded truly impressive results. The restorations showed close-to-perfect marginal quality. Virtually no material-related flaws were detected. Therefore, the vast majority of the restorations received a "Good" to "Excellent" rating. Only few deviations were found, which are probably due to my own shortcomings as a user. This material doubtless enables clinicians to create long-lasting, esthetic tooth restorations."

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