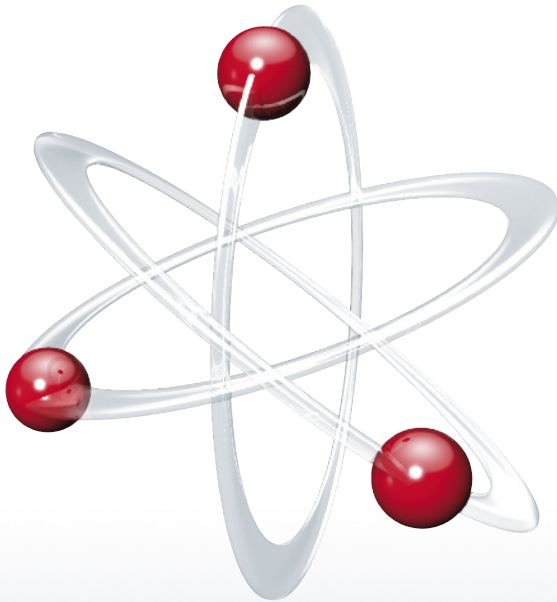




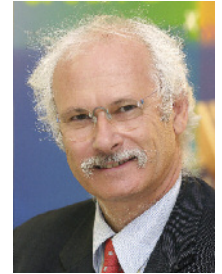
Clinical Studies 2011



Tetric EvoCeram[®]
Direct Composite Technology has **Evo**lved.

Prof. Dr Jean-François Roulet

Preface



Since the development of composite materials in the middle of the 20th century, the application of this type of material for direct restorative treatment has steadily increased. Today, restorative dentistry cannot be imagined without composite materials. Many innovations in composite technology, such as pre-polymers and the radiopaque ytterbium trifluoride, have originated in the Research and Development Department of Ivoclar Vivadent.

What was once considered an innovation has become well-established and proven technology today. Tetric EvoCeram® is the result of Ivoclar Vivadent's many years of experience and expertise in the field of composite technology. Tetric EvoCeram offers convincing features such as low polymerization shrinkage, low shrinkage stress, high radiopacity and high wear resistance. Moreover, the product is distinguished by its good handling properties and it enables stress-free application. In contrast to other composites, Tetric EvoCeram offers the **longest working** with the **shortest curing time**. Furthermore, it blends seamlessly with **natural dentition**, which is attributable to the optimally coordinated light refraction indices of fillers, monomer matrix and nano-colour pigments.

Apart from these parameters, one of the major factors that influences the decision to buy a composite restorative is its **clinical performance**. Only clinical studies (conducted *in vivo*) can ultimately provide conclusive evidence of how a product will perform over time. This booklet summarizes the results of up to **5-years** of important *in vivo* studies on **Tetric EvoCeram** and illustrates the excellent long-term performance of this material.

Tetric EvoCeram: Proven clinical performance for more than five years

Clinical studies represent the ultimate test for any restorative material. Unfortunately, these studies require considerable time until they deliver reliable long-term data. Consequently, the more *in vivo* or *in situ* studies are conducted and the longer their observation period is, the more reliable are their findings with regard to the long-term performance of the direct restorative materials investigated. More than 85 million Tetric EvoCeram restorations have been placed worldwide since the product was launched on the market. In the 5-year studies described in this booklet, not even a single restoration fabricated with the time-tested universal composite Tetric EvoCeram had to be replaced.

Clinical studies usually involve the placement of a certain number of restorations (N), which are first assessed after a short period of time (at "baseline"). Within the framework of clinical studies, restorations are normally evaluated according to USPHS criteria, which were originally established by Ryge and Snyder (1973, 1980) for the United States Public Health Service. They include criteria such as "Colour Match", "Marginal Adaptation", "Anatomical Form", "Marginal Discolouration", etc. Based on these criteria evaluators decide on whether or not a restoration is clinically acceptable. In this context, the following codes are used to classify the restorations: **A**lpha ("ideal"), **B**ravo ("acceptable"), **C**harlie ("unsatisfactory but reparable") and **D**elta ("unacceptable, replacement necessary"). The evaluations are repeated at various intervals (e.g. after 6, 12, ...60 months). For reasons of clarity, only the latest evaluations are presented here, e.g. the 5-year results in the case of the study conducted by Dr Muñoz et al. Only restorations that received the ratings Alpha and Bravo for all the parameters were considered to be clinically successful.



Starting situation



Result after placement



After 6 years

Overview of clinical studies conducted with Tetric EvoCeram

Authors	Indications	Observation period (years)
Dr C. Muñoz/Dr. J. Dunn, Loma Linda Univ., California, USA	Class III, IV	5
Prof. Dr P. Lambrechts, Univ. of Leuven, Belgium	Class I, II	5
Dr A. Peschke, R&D Clinic, Ivoclar Vivadent, Schaan, Liechtenstein	Class I, II	5
Prof. Dr A Cerruti, Univ. of Brescia, Italy	Class I, II	4
Prof. Dr J. van Dijken, Univ. of Umea, Sweden	Class I, II	3
Prof. Dr J. van Dijken, Univ. of Umea, Sweden	Class I, II	3
Dr C. Gernhardt / Prof. Dr H.-G. Schaller, Univ. of Halle, Germany	Class I, II	2
Dr M. A. Latta, Creighton Univ., Nebraska, USA	Class V	1
Prof. Dr R. Hickel / Dr. J. Manhart, Univ. of Munich, Germany	Class I, II	0.5

Dr C. Muñoz and Dr J. Dunn

Tetric EvoCeram in Class III and IV restorations

Study design

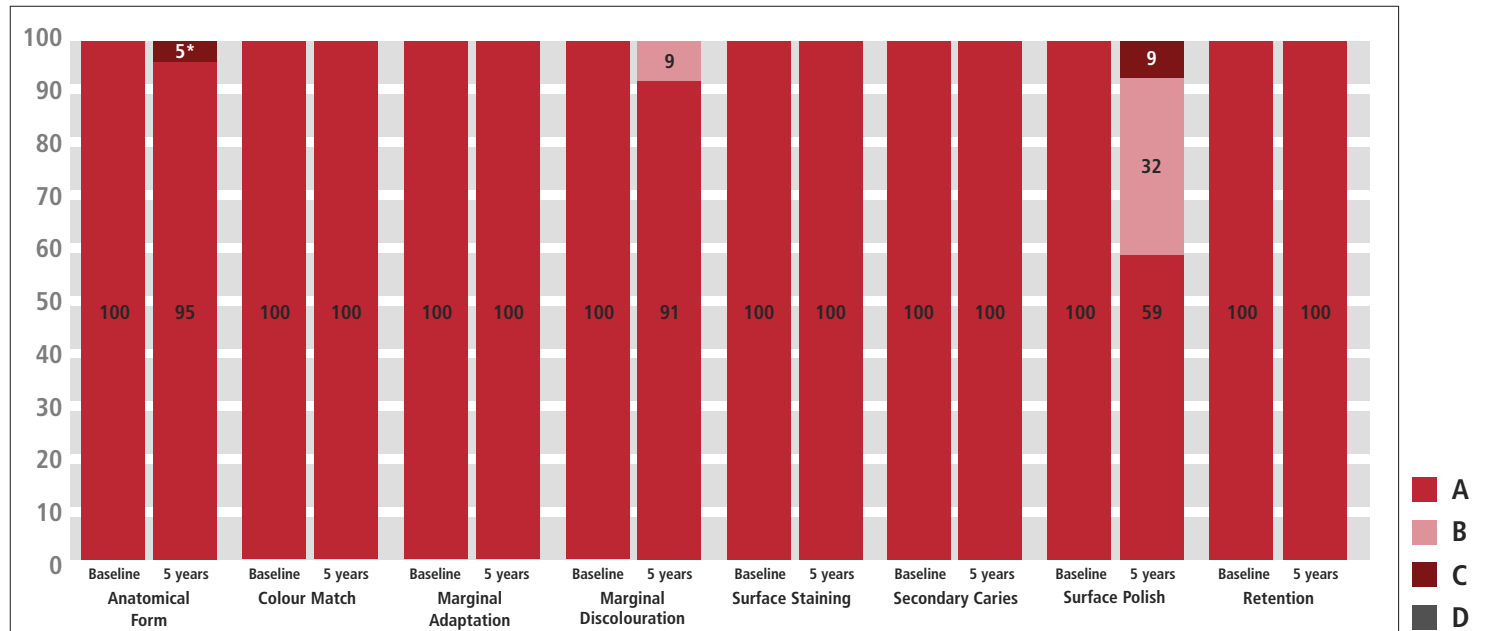
The aim of this clinical study was to evaluate the long-term clinical performance of Tetric EvoCeram in the anterior region. Forty-two Class III and Class IV cavities were filled using Tetric EvoCeram in conjunction with ExciTE® adhesive. The two materials were used for the restoration of the central and lateral incisors and the canines, the repair of incisal edges, the closure of diastemas and the fabrication of direct veneers. The composite and the adhesive were light-cured with the high-performance LED bluephase curing light. Twenty-two of the restorations were available for examination after 5 years.

Clinical assessment

The retention rate was 100% after 5 years of service. This means that none of the restorations was rated "unacceptable" and had to be replaced. At recall after 5 years, neither secondary caries nor surface discolouration were observed. In addition to the material's good clinical performance, the clinicians considered the good handling properties, natural shade blend and excellent marginal adaptation to be remarkable advantages of Tetric EvoCeram. The findings after 5 years show that Tetric EvoCeram is a good clinical choice for anterior restorations, as it retains its good physical and esthetic properties over time.

Tetric EvoCeram after 5 years

[%] of restorations



*One veneer showed slight fracture of the incisal edge. However, this did not detrimentally affect the marginal integrity so that the veneer did not have to be replaced.

Prof. Dr P. Lambrechts

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

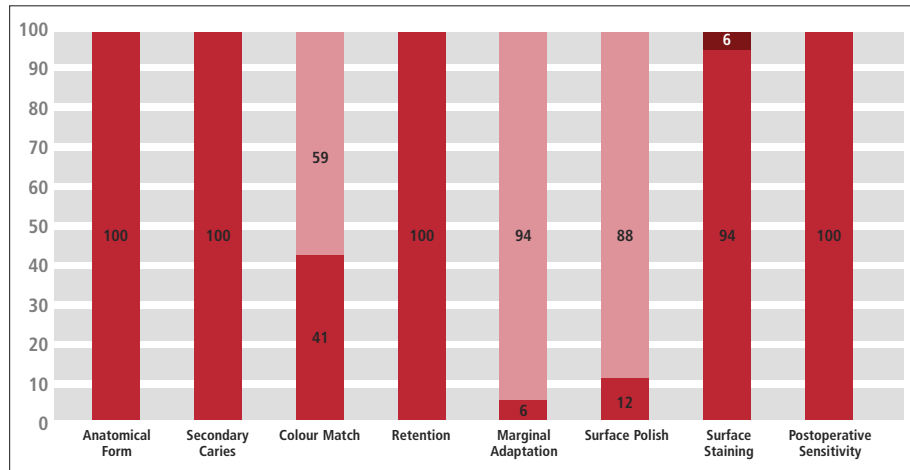
Study design

The purpose of this clinical study was to evaluate the long-term clinical performance of Tetric EvoCeram, in particular in comparison with the time-tested predecessor material Tetric Ceram. For this purpose, 17 Tetric EvoCeram restorations and 16 Tetric Ceram restorations were placed in Class I and II cavities. In both groups, the self-etching AdheSE® was used as the adhesive. All the 33 restorations were available for examination after 5 years.

Clinical assessment

During the observation period of 5 years, none of the Tetric EvoCeram restorations had to be replaced. No restoration showed secondary caries (= 100% A ratings). In addition, 100% of the restorations received an A rating with regard to anatomical form. Ninety-four percent of the Tetric EvoCeram restorations were rated clinically acceptable (A and B) after the service life of 5 years. The data available attest to the excellent clinical performance of Tetric EvoCeram after 5 years of service.

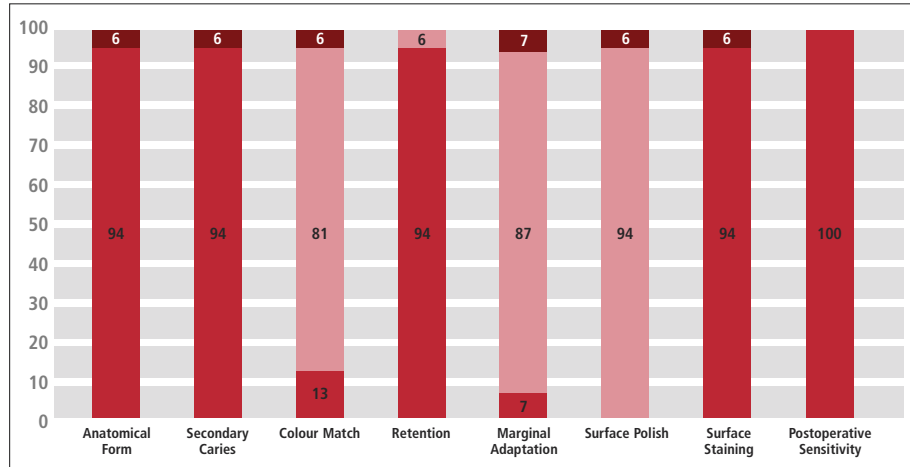
[%] of restorations



Tetric EvoCeram after 5 years



[%] of restorations



Tetric Ceram after 5 years



(After several years of service, both Tetric Ceram and Tetric EvoCeram restorations increasingly received B ratings with regard to the criterion "Marginal Adaptation". However, this may be due to the adhesive chosen, not the restorative material.)

Dr A. Peschke

Tetric EvoCeram in Class I and II cavities

Study design

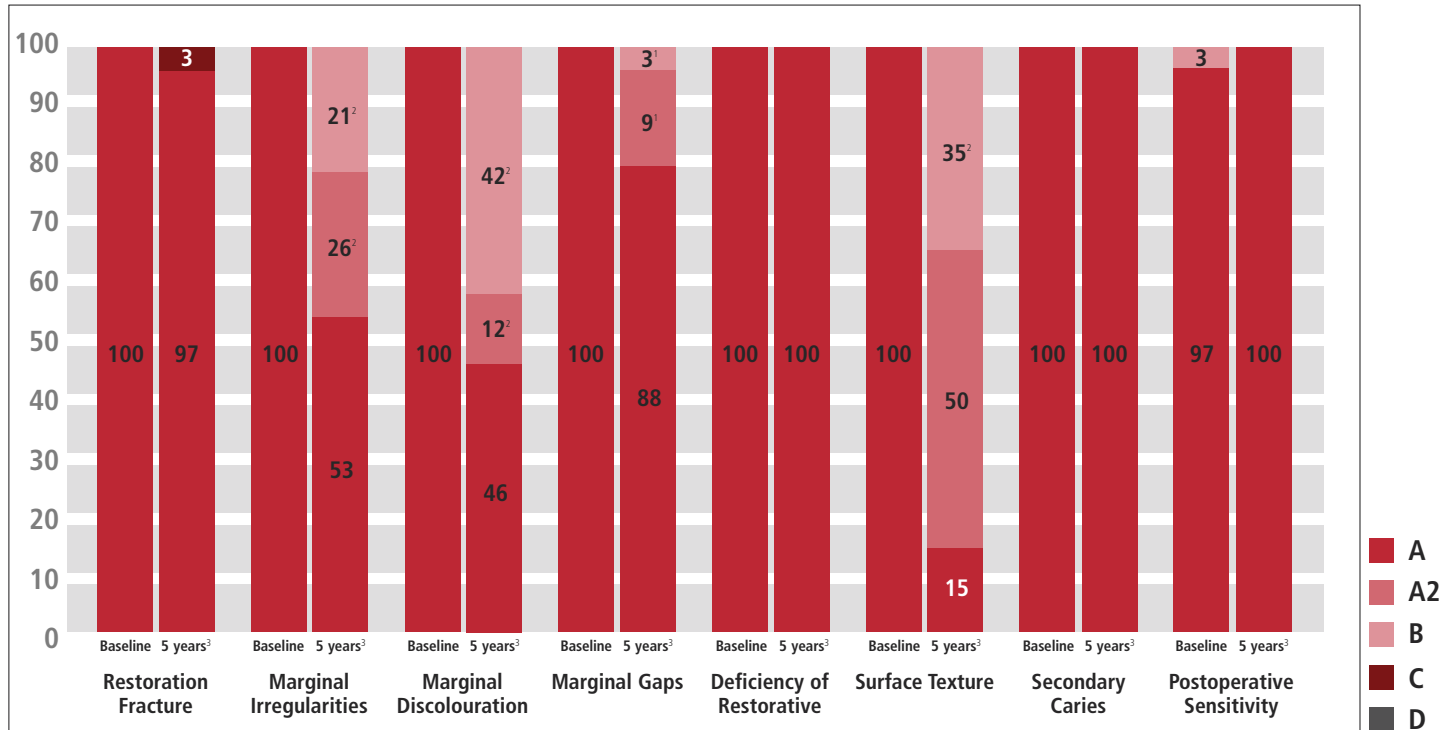
Within the framework of this clinical study, 50 Class I and II cavities were restored with Tetric EvoCeram in conjunction with the total-etch adhesive Syntac. The restorative material was light-cured with Astralis 10 using the Pulse mode. Subsequently, the restorations were polished using the three-step polishing system Astropol. After 5 years, 34 restorations were still available for evaluation.

Clinical assessment

With a survival rate of 100%, Tetric EvoCeram showed a very high success rate over the period of 5 years. Thirty-eight percent of the restorations were still rated clinically "excellent" or "good" and 59% were rated "satisfactory". Only one restoration had to be repaired due to minor material fracture. Marginal leakage was only noted in limited areas along the length of the restoration margin. Overall, this combination of materials shows reliable clinical performance over a period of 5 years.

Tetric EvoCeram: At baseline and after 5 years

[%] of restorations



¹⁾ Max. 10% of the length of the restoration margin were affected.

²⁾ Max. 25% of the length of the restoration margin were affected.

³⁾ FDI criteria were applied (R. Hickel et al. 2010); The authors distinguished between A = clinically excellent, A2 = clinically good,

B = clinically sufficient/satisfactory, C = clinically unsatisfactory but repairable and D = clinically poor, replacement necessary.

Prof. Dr A. Cerutti

Comparison of two different polymerization protocols: Tetric EvoCeram in Class I and II cavities

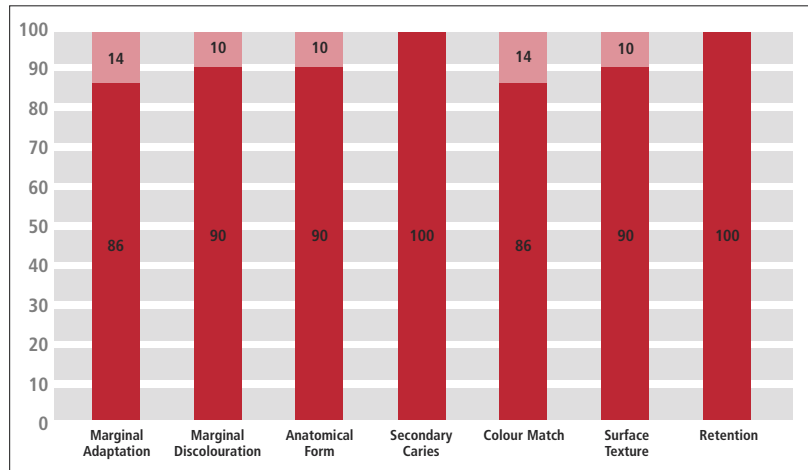
Study design

This clinical study examined the effect of two different polymerization protocols on the quality of Class I and II restorations. Two restorations each were placed in 50 patients using a split-mouth design. One restoration was cured at a light intensity of 600 mW/cm² for 20 s per increment, while the other one was cured at a light intensity of 1200 mW/cm² for 10 s per increment. The restorative material used was Tetric EvoCeram (with Excite as the adhesive). All the restorations placed were available for examination after 4 years.

Clinical assessment

The investigation focussed on evaluating the effect of different curing modes on the marginal integrity of restorations. The results of the study show that marginal integrity is not influenced by the light intensity used. Both test set-ups led to clinically successful results. With retention values of 98% or 100% depending on the polymerization protocol used, Tetric EvoCeram restorations showed a very high success rate after 4 years. The different parameters exclusively received A (“ideal”) and B (“acceptable”) ratings, which attest to the excellent clinical performance of Tetric EvoCeram restorations after 4 years of service. The result achieved with regard to all the parameters investigated confirms that the material is highly suitable for dental restorations in the posterior region.

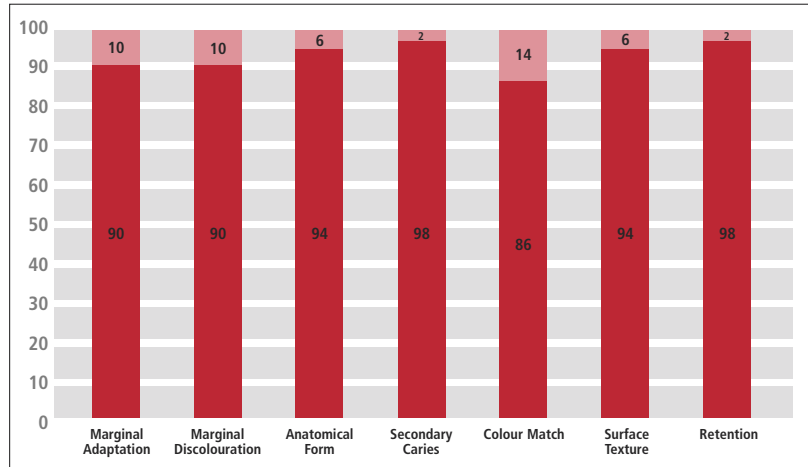
[%] of restorations



20 s, 600 mW/cm², Tetric EvoCeram after 4 years



[%] of restorations



10 s, 1200 mW/cm², Tetric EvoCeram after 4 years



Prof. Dr J. van Dijken

Tetric EvoCeram in Class I and II cavities

Study design

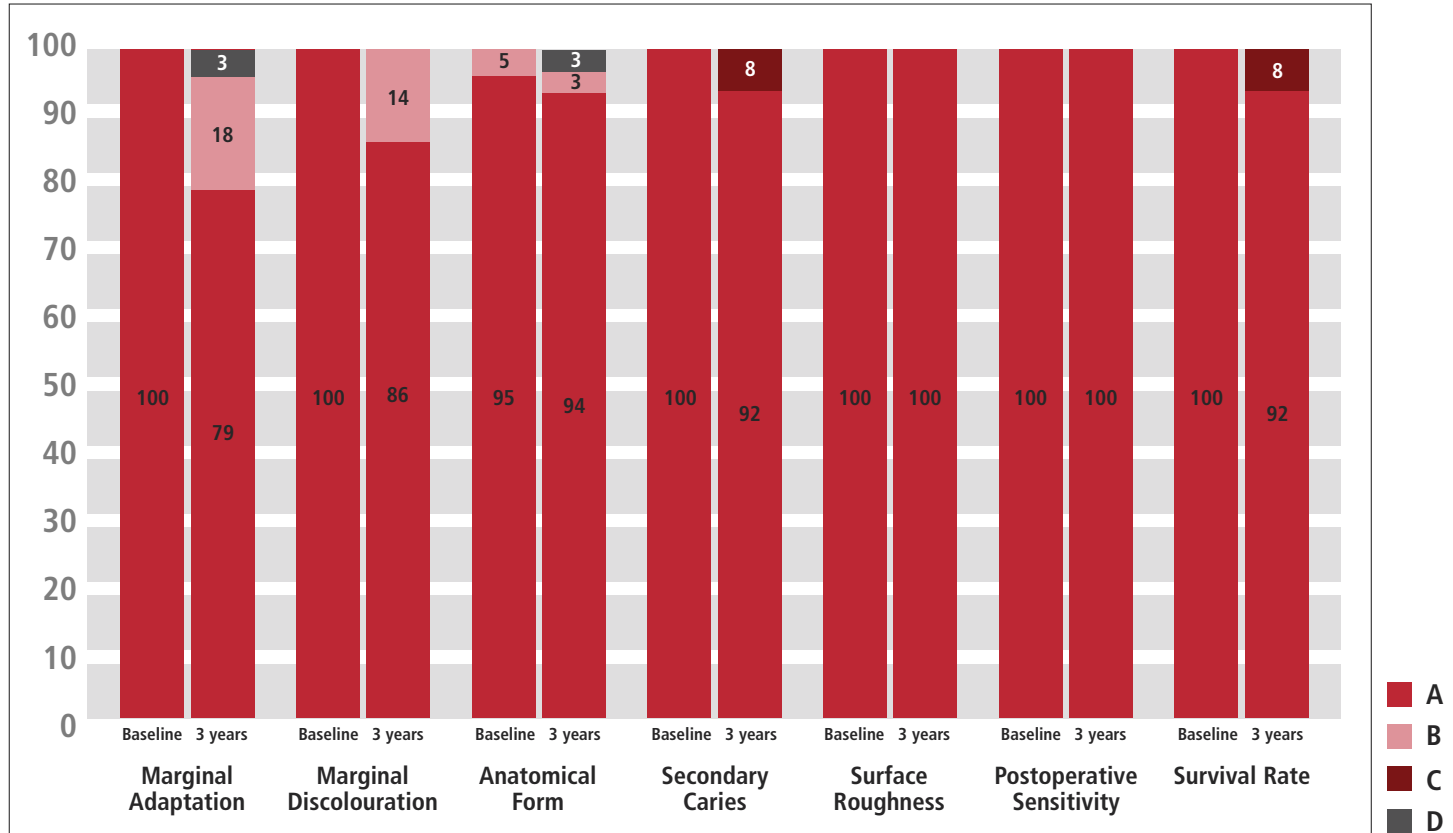
The purpose of this study was to assess the long-term clinical performance of Tetric EvoCeram. Forty cavities in molars and premolars (8 Class I and 32 Class II cavities) were restored with Tetric EvoCeram (using Excite as the adhesive). Individual increments of max. 2 - 3 mm were applied and light-cured for 40 seconds with Astralis 7 using the HIP mode. The restorations were assessed one month after placement (at "baseline") as well as after 36 months. A total of 38 restorations were available for evaluation at the final recall after 3 years.

Clinical assessment

During the 3-year study period, three fillings were rated "unacceptable" due to secondary caries and had to be replaced. This corresponds to an annual failure rate of 2.6%. The fact that the Tetric EvoCeram restorations demonstrated consistent marginal integrity and surface texture over several years is particularly noteworthy. Hence, Tetric EvoCeram offers ideal prerequisites for the fabrication of durable Class I and II restorations.

Tetric EvoCeram: At baseline and after 3 years

[%] of restorations



Prof Dr. J. van Dijken

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

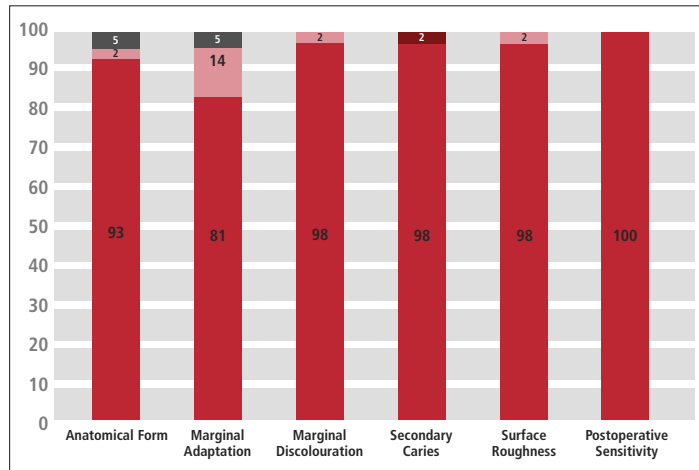
Study design

The purpose of this clinical study was to evaluate the clinical performance of Tetric EvoCeram, in particular in comparison with the time-tested predecessor material Tetric Ceram. For this purpose, 62 Tetric EvoCeram restorations and 62 Tetric Ceram restorations were placed in a total of 52 patients using a split-mouth design. In both groups, Excite was used as the adhesive. All the teeth treated were vital and in contact with the antagonists and adjacent teeth. Individual increments of max. 2 - 3 mm were placed. Each increment was light-cured for 20 s using Astralis 7 in the HIP mode.

Clinical assessment

The overall success rate of Tetric EvoCeram after 36 months was 95%. The handling properties of Tetric EvoCeram were rated "good" and "easily adaptable". Tetric EvoCeram showed slightly better stability than Tetric Ceram during sculpting and contouring. After polishing, the restorations showed a smooth surface finish. After 3 years, the surface texture was still rated "smooth" for all the restorations except one Tetric EvoCeram restoration. At recall after 3 years, two Tetric EvoCeram restorations and one Tetric Ceram restoration had to be replaced. Both studies conducted by Dr van Dijken show that the clinical performance of Tetric EvoCeram is excellent, both in the medium and long term.

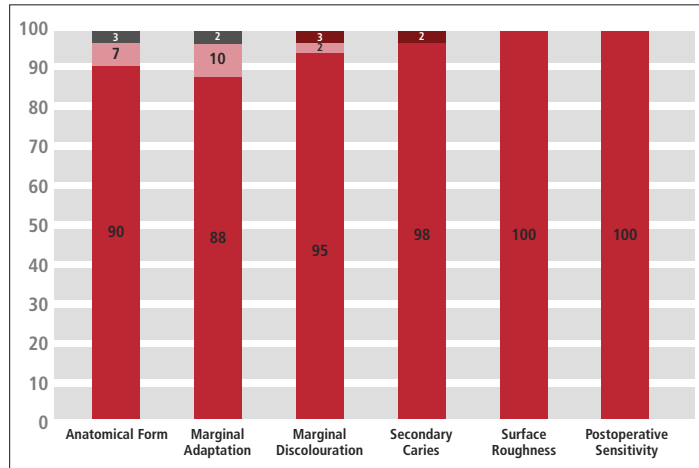
[%] of restorations



Tetric EvoCeram after 3 years

- A
- B
- C
- D

[%] of restorations



Tetric Ceram after 3 years

- A
- B
- C
- D

Dr Christian Gernhardt and Prof. Dr H.-G. Schaller

Tetric EvoCeram with and without Tetric Flow in Class I and II cavities

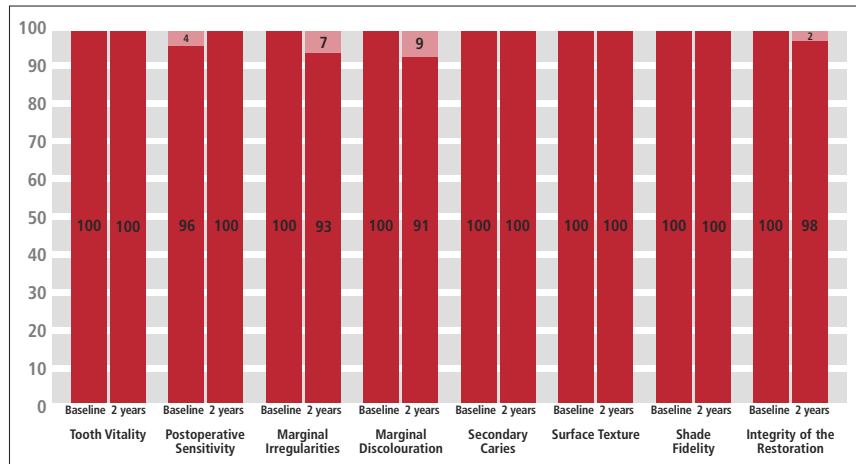
Study design

The purpose of this study was to evaluate the clinical performance of AdheSE One in combination with Tetric EvoCeram and Tetric Flow in Class I and II cavities. Particular attention was placed on investigating whether or not the use of Tetric Flow affected the marginal integrity of the restorations and the occurrence of postoperative sensitivity. Fifty pairs of Class I and II cavities were either filled exclusively with Tetric EvoCeram or in combination with Tetric Flow, which was placed as an initial layer (0.5 mm). The restorations were light-cured with the bluephase polymerization light using the Soft Start mode (SOF). Forty-three restorations of the group “without Tetric Flow” and 44 restorations of the group “with Tetric Flow” were available for examination after 2 years.

Clinical assessment

After 24 months, both groups received 100% A ratings for the criteria of Tooth Vitality, Postoperative Sensitivity, Secondary Caries, Surface Texture and Shade Fidelity. Minor marginal discolouration and marginal irregularities were observed. Three patients complained about postoperative sensitivity over a period of 24 hours after placement. In one patient the sensitivity persisted for one week. Overall, no significant difference was found between the two test groups. Consequently, this 2-year study also confirms the high success rate of 100% of Tetric EvoCeram restorations, regardless of whether or not a flowable composite such as Tetric Flow is used as an initial layer.

[%] of restorations

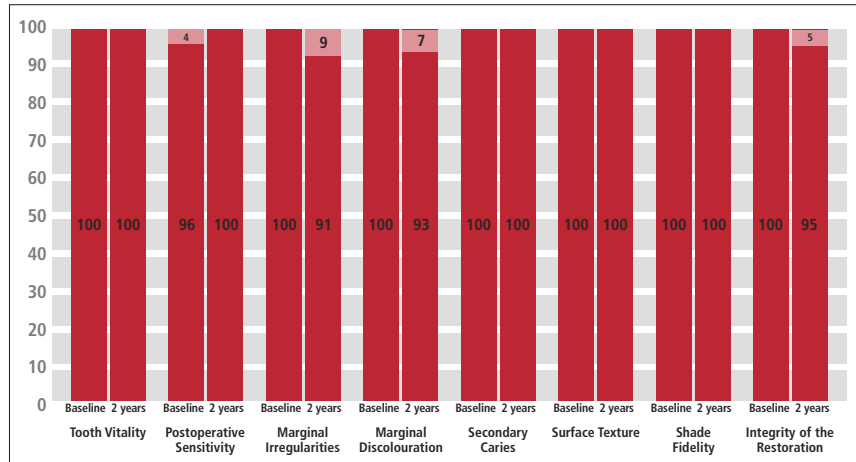


Tetric EvoCeram: At baseline and after 2 years

Without Tetric Flow

- A
- B
- C
- D

[%] of restorations



With Tetric Flow

- A
- B
- C
- D

Dr M. A. Latta

Tetric EvoCeram in Class V cavities

Study design

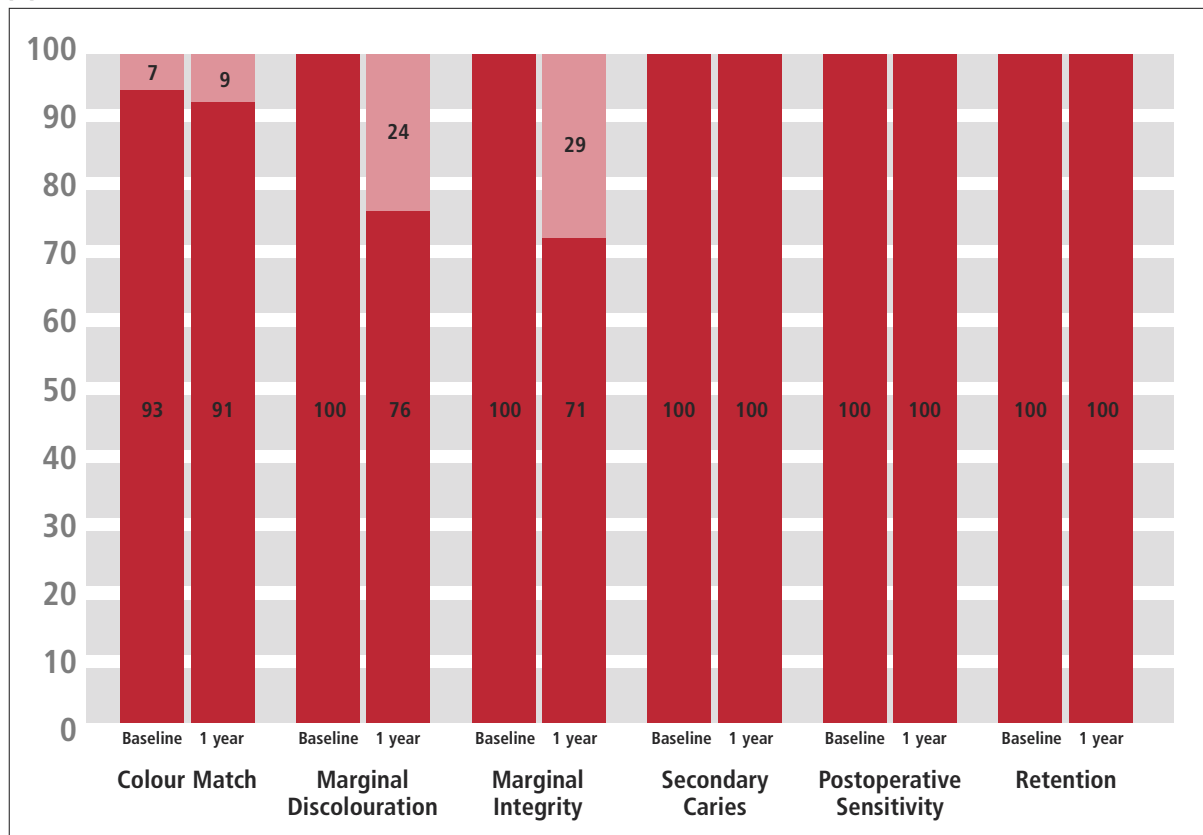
The aim of this clinical study was to evaluate the clinical performance of Tetric EvoCeram in Class V cavities. Fifty-five cavities were restored using Tetric EvoCeram (in conjunction with the self-etching adhesive AdheSE). The restorations were light-cured with the high-performance LED curing light bluephase. Twenty-six patients with 45 restorations were available for examination after 12 months.

Clinical assessment

With 100% retention after 12 months of service, Tetric EvoCeram shows a very high success rate, which impressively attests to the suitability of the material also for restoring class V cavities. The fact that the tooth neck sensitivity, which was present prior to the treatment in some cases, disappeared after the restorations had been placed is particularly noteworthy. In addition, the clinicians considered the convenient handling, excellent colour match, quick polishing and excellent retention of sheen of the product to be outstanding benefits. Overall, the clinical performance of the material was rated "outstanding".

Tetric EvoCeram: At baseline and after 1 year

[%] of restorations



(After 12 months, the material increasingly received B ratings for the criteria "Marginal Integrity" and "Marginal Discolouration".

Similar observations were made in clinical studies which involved other self-etching adhesives. This is most probably due to the type of adhesive chosen, not the restorative material.)

Prof. Dr R. Hickel and Dr J. Manhart

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

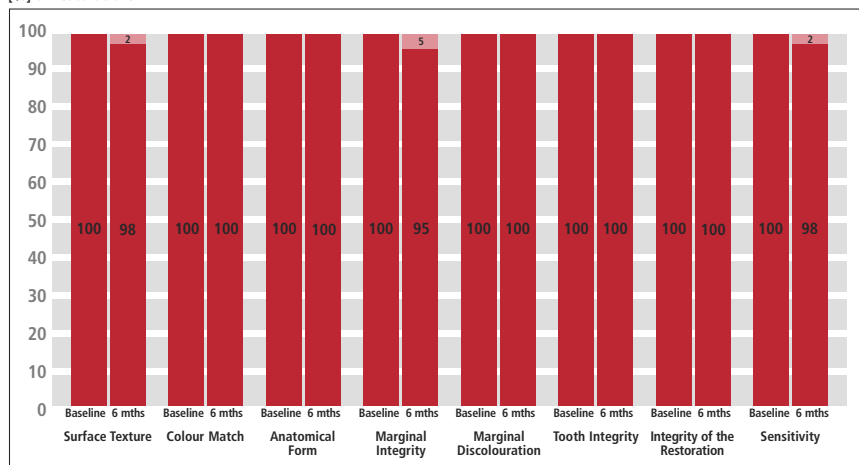
Study design

The objective of this clinical study was to evaluate the long-term clinical performance of Tetric EvoCeram Class I and II restorations, in particular in comparison with the time-tested predecessor material Tetric Ceram. For this purpose, 56 Tetric EvoCeram restorations and 43 Tetric Ceram restorations were placed. In both groups, the self-etching AdheSE was used as the adhesive. Forty-one Tetric EvoCeram and 32 Tetric Ceram restorations were assessed at recall after 6 months.

Clinical assessment

Tetric EvoCeram showed a success rate of 100% after 6 months of service. It received predominantly A ratings for the different criteria. Therefore, Tetric EvoCeram offers ideal prerequisites for the fabrication of long-lasting restorations.

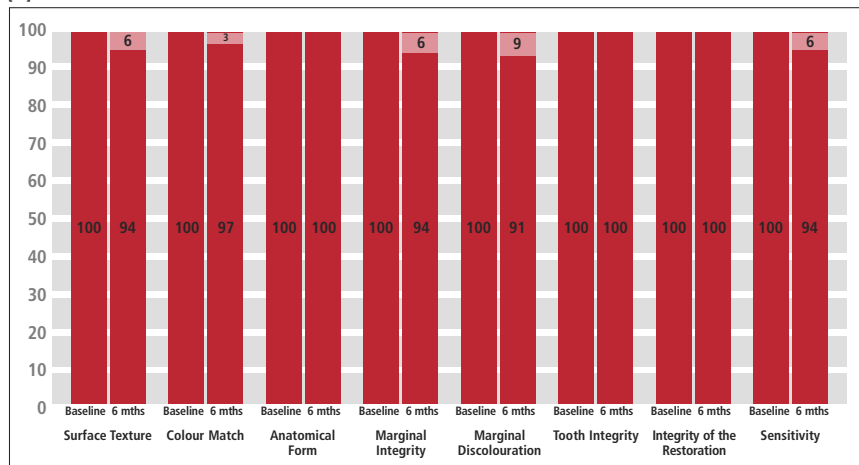
[%] of restorations



Tetric EvoCeram: At baseline and after 6 months

- A
- B
- C
- D

[%] of restorations



Tetric Ceram: At baseline and after 6 months

- A
- B
- C
- D

Literature:

Ryge, G. (1980): "Clinical criteria", *Int. Dent. J.*, 30 (4), 347-58.

Ryge, G. & Snyder, M. (1973): "Evaluation the clinical quality of restorations", *JADA*, Vol. 87, 369-377.

Hickel, R. et al. (2010): "FDI World Dental Federation – Clinical Criteria for the Evaluation of Direct and Indirect Restorations – Update and Clinical Examples", *J. Adhes. Dent.*, 12, 259-272.

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