

Scientific Documentation

TETRIC

**Research and Development
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1. Introduction

Tooth-coloured restorations are not an invention of our time. Ceramic inlays were used as aesthetic restorations as early as 1856 (Hoffmann-Axthelm, 1973). Other applications of indirect tooth-coloured restorations were reported in 1888 (Land) and 1891.

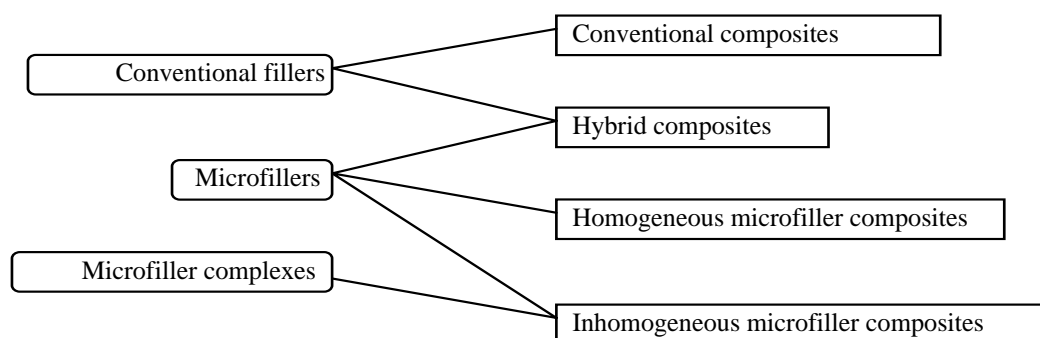
The development of direct tooth-coloured restoratives began in 1871 with silicate cements. Self-curing acrylates have been used as a dental restorative since the 1940s. Silicate cements as well as acrylates demonstrated considerable disadvantages. Silicate cements were water soluble, brittle, and prone to dehydration. Acrylates demonstrated a low degree of dimensional stability.

The sixties saw the introduction of composites. Bowen (1955, 1956, 1958, 1962) considerably contributed to their development. Composites are a mixture of at least two chemically different materials with a clearly delineated bonding layer (Phillips, 1981). The large monomer molecule used by Bowen reduced polymerization shrinkage to 2-4% (v/v) as opposed to 20% (v/v) for acrylates.

Over the past 20 years, numerous restoratives have been developed based on Bowen's idea of mixing an organic matrix with inorganic materials. Today, most commercial composites are based on Bis-GMA or on other bifunctional methacrylate monomers.

Two options are available for polymerization: chemical and photochemical curing. Basically, all composites can be adjusted to both types of polymerization. Autopolymerization for chemically activated materials begins after mixing (2 components) and is based on a redox system, the oxidative of which is usually benzoyl peroxide and the reducing agent a tertiary amine (amine peroxide redox system). A combination of diketones or aromatic ketones (e.g. campherchinon) and reducing agents (e.g. tertiary amine) are usually used for photochemical curing (1 component).

The bond between the inorganic fillers and the organic matrix is achieved with silane.



Classification of Composites (Lutz et al., 1983)

The properties of composites are greatly influenced by the type of filler used. Hence, Lutz et al. (1983) recommend classifying composites according to their fillers. These materials differ in their manufacturing technique, particle size, and chemical composition (Figure).

Until a few years ago, composites for posterior teeth could hardly compete with amalgam and gold. The aesthetic restorations lasted only for a limited time because of marginal fractures,

abrasion, bulk fractures, and secondary caries. As a result of improved material properties and working techniques, however, composites can now be successfully used as universal restorative materials. Apart from the hybrid composites, only a few conventional fine particle composites, e.g. Z100, and the inhomogeneous microfiller composite Heliomolar RO (CRA Newsletter, 1994 a, b) are of practical significance as universal composites.

Conventional composites	Hybrid composites	Homogeneous microfiller composites	Inhomogeneous microfiller composites
Concise Prisma-Fil Marathon Z 100	Brilliant Charisma Herculite XR Prisma APH, TPH P10, P30, P50 Pertac Hybrid <i>Tetric</i>		Distalite Durafil <i>Heliomolar RO</i> <i>Helio Progress</i> <i>Isomolar</i> <i>Isopast</i> Silux / Silux Plus

Classification of restorative composites (Krejci and Lutz, 1994)

2. Technical Data Sheet

Product: **TETRIC**

Type of material: **Light curing, fine particle microhybride composite**

Standard - Composition:

(in weight %)

Bis-GMA, Triethylenglycole Dimethacrylate, Urethane dimethacrylate	18.8
Barium glassfiller, Ytterbiumtrifluoride, High dispersed silica, Mixed oxide	81.0
Catalysts and Stabilizers	0.2
Pigments	< 0.1

Physical properties:

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

Flexural strength	140 MPa
Flexural modulus	11500 MPa
Water absorption	21.5 $\mu\text{g}/\text{mm}^3$
Water solubility	1.0 $\mu\text{g}/\text{mm}^3$
Radiopacity	400 % Al
Depth of cure (dependent upon shade)	> 4.5 mm
Compressive strength	300 MPa
Vickers hardness HV 0.5/30	800 MPa
Transparency (dependent upon opacity)	9 - 16 %
Density	2.26 g/cm^3
Filler content	81.0 wt.% 62.0 vol.%

3. Properties of Tetric

The following objectives were primarily pursued in the development of Tetric:

- **Mechanical properties:** *Low susceptibility to fracturing; abrasion resistance*
- **Optical properties:** *High degree of translucency, natural-looking shading*
- **Working properties:** *Easy handling*
- **Surface characteristics:** *Smooth, polishable to a high gloss*

In addition, a restorative with the following properties was developed:

- **Low polymerization shrinkage**
- **Fluoride release**
- **Radiopacity**

3.1. Mechanical Properties

A direct correlation between the individual mechanical properties determined in the laboratory and the clinical behaviour of a restorative material is not clearly given, since a number of material properties come together to achieve clinical success. The individual material properties often mutually influence one another (e.g. water absorption and surface hardness). In some cases they even overlap (e.g. strength of the filler and the matrix). It is often criticized that the mechanical properties are determined under ideal, standardized conditions in the laboratory. Hence, it is questionable if these values can be achieved in clinical applications. As a result, clinical behaviour must always be taken into account when testing the mechanical properties.

The significance of the in vitro examinations, however, should not be underestimated. Mechanical properties must be determined to ensure quality assurance during the development and production of the composite. Furthermore, these values can be used to interpret clinical results, thus contributing to the further development of the restorative material.

3.2. Optical Properties

The appearance of the natural tooth is determined by its shade as well as its translucency (light transmitting capacity) and surface characteristics. For tooth-coloured restoratives, the shade is determined by pigments and the surface characteristics by the filler composition. An adequate degree of translucency, however, is difficult to achieve for most materials. Natural tooth enamel is highly translucent. Up to 70 % of the light falling on a 1 mm thick ground section penetrates it. Dentin is considerably less translucent. By contrast, a 1 mm thick ground section allows little more than 30 % of the light falling on it to penetrate (McLean 1981). In order to achieve an aesthetic restoration, i.e. a tooth-like, undetectable restoration, the person conducting the treatment ideally needs a restorative with both higher and lower translucency.

A high degree of translucency also has a positive influence on the curing depth, resulting in improved physical properties and a higher degree of biocompatibility.

Hence, the primary objective in the development of Tetric was to achieve a high degree of translucency. This objective was difficult to fulfil because of the light dispersion of fine particle hybrids. The opaqueness of a composite material is caused by fine particle fillers which have a different refractive index from the matrix that surrounds them. If the diameter of the particles is larger than the wavelength of the falling light, the opaqueness is caused by refraction and reflection. When smaller particles are used, opaqueness is caused by diffraction (Vogel 1979). Four coordinated fillers were used for Tetric to solve this problem. The critical pyrogenic silicon dioxide, however, was partially replaced by spheroid mixed oxide (sol-gel process) (Ivoclar-Vivadent Report No. 7, 1992).

3.3. *Handling*

Consistency, stability of form, and thus handling are subjective properties. Tetric's relatively low stickiness and high stability of form allow users to adapt the composite to the cavity wall with greater precision than is possible with pastes that stick to the instrument. Furthermore, the stability of form enables easier modelling of fissures and cusps.

3.4. *Surface Characteristics*

The surface structure is also important for clinical success. In addition to being unaesthetic, rough surfaces help to accumulate plaque. Furthermore, a rough surface influences the abrasion behaviour of the composite itself as well as its abrasion of the enamel antagonist. The objective is to achieve the smoothest possible surfaces (finishing and polishing). The effect of toothpaste and toothbrush abrasion on the initially smooth surfaces of composites must also be taken into consideration (Willems et al., 1991; Dijken et al., 1987; Roulet et al., 1984).

3.5. *Polymerization Shrinkage*

Shrinkage is determined by the composition and reaction of the monomers, and the filler content. The individual resins (monomers) demonstrate different degrees of polymerization shrinkage. The selection is limited because the monomer composition influences other properties (viscosity, reactivity, refractive index). As a low monomer content will result in less shrinkage, the highest possible filler content should be achieved. The amount of filler added, however, cannot be increased arbitrarily. If the filler content exceeds a certain limit a homogenous paste can no longer be achieved. Furthermore, as the filler content directly affects the consistency, it cannot be determined arbitrarily.

3.6. *Fluoride Release*

The effect of fluoride ions in preventing caries is generally accepted and thoroughly documented (Ten Cate and Duysters, 1983). The potential to prevent caries has also been determined for other restorative materials containing fluoride ions, for example, silicate cements and glass ionomers. Hence, the development of composite restoratives with fluoride release was also undertaken. Achieving the highest possible fluoride concentration, however, should not be the sole objective. The released fluoride should not have a negative effect, for example, discolouration or limitation of physical and mechanical properties, on the restorative composite. As a result, the selection is limited to a few slightly soluble fluorides.

Vivadent uses ytterbium trifluoride (YbF_3 , patented worldwide by Vivadent) in composite restorative materials. Numerous in vitro studies (Arends et al., 1988, 1989 / Tysowsky et al., 1988) established that a significant level of fluoride absorption in the dental hard tissue adjacent to the restoration had taken place, although only a small amount of fluoride ions had been released. Constant physical and mechanical properties were also determined during immersion in water over a period of more than a year (Vivadent R&D). The application of ytterbium trifluoride has been proved successful in long-term clinical tests involving Heliomolar radiopaque (Leinfelder and Mazer, 1992).

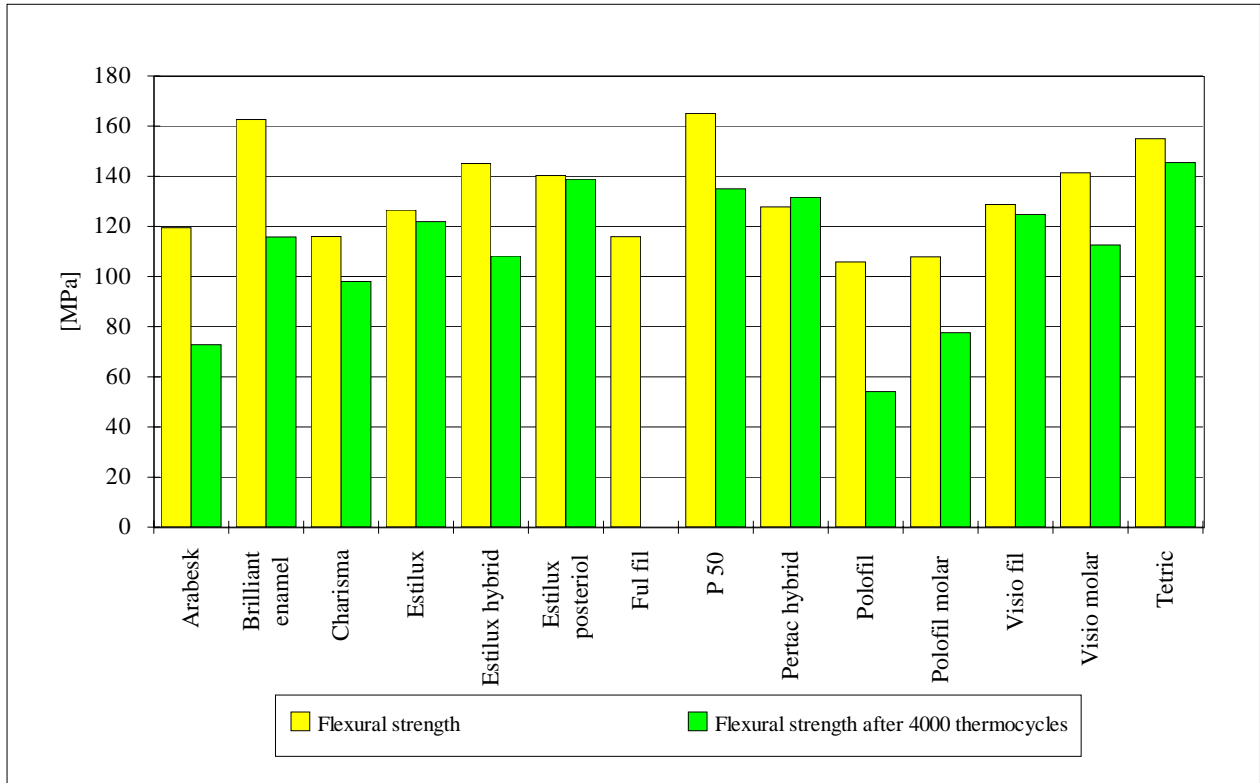
3.7. *Radiopacity*

Adequate radiopacity is necessary for diagnosing secondary caries, excessive or insufficient amounts of restorative, trapped air, and other imperfections in otherwise inaccessible posterior restorations. The lowest degree of radiopacity for restorative materials has been determined as that of dental enamel (250 % Al) (Lutz 1980). Radiopacity of more than 300 % Al is required for a clear contrast on diagnostic X-rays (Lutz 1980). Only a few of the composite restoratives, however, demonstrate radiopacity of more than 250 % Al. Apart from providing Tetric with fluoride release, ytterbium trifluoride also ensures a high degree of radiopacity.

4. Physical Values (in vitro studies)

4.1. Mechanical Properties

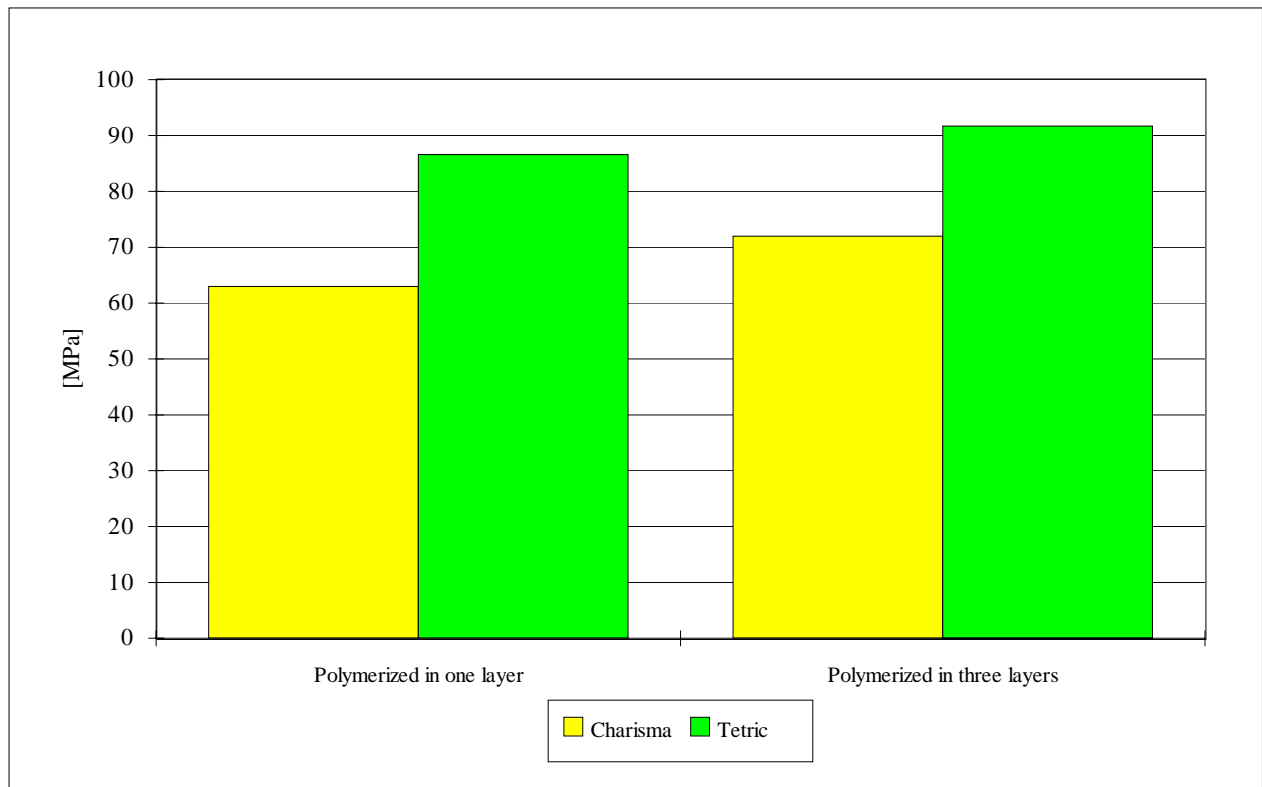
4.1.1. Flexural Strength of Hybrid Composites Before and After Thermocycling



Rzanny et al., 1995

Conclusion: Tetric demonstrates one of the highest degrees of flexural strength of the hybrid composites examined. After loading the materials according to conditions simulating those of the oral cavity, Tetric demonstrated the highest flexural strength.

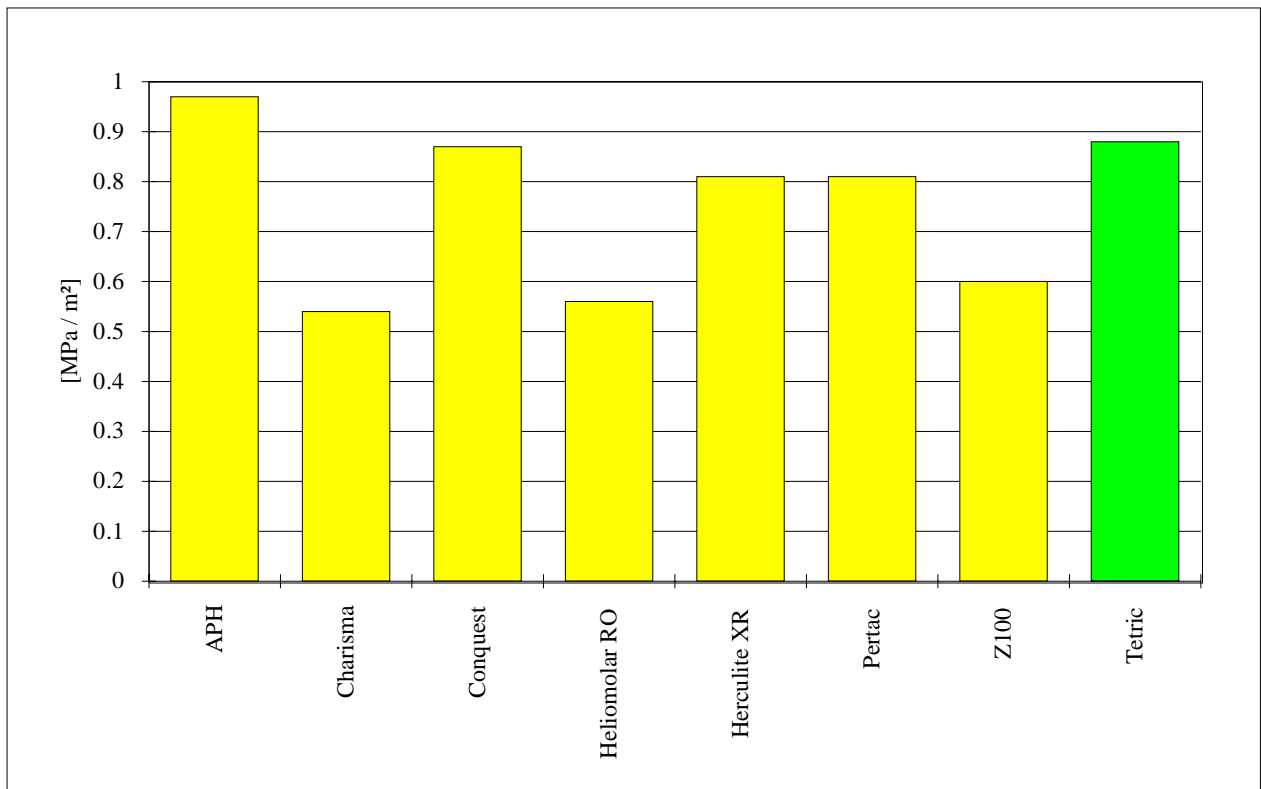
4.1.2. *Biaxial Flexural Strength*



Sindel and Petschelt, 1995

Conclusion: In contrast to one-step polymerization, layering results in less shrinkage and achieves a higher degree of flexural strength. Compared with Charisma, Tetric demonstrates a significantly higher degree of flexural strength for both working techniques.

4.1.3. Fracture Resistance (K_{IC})

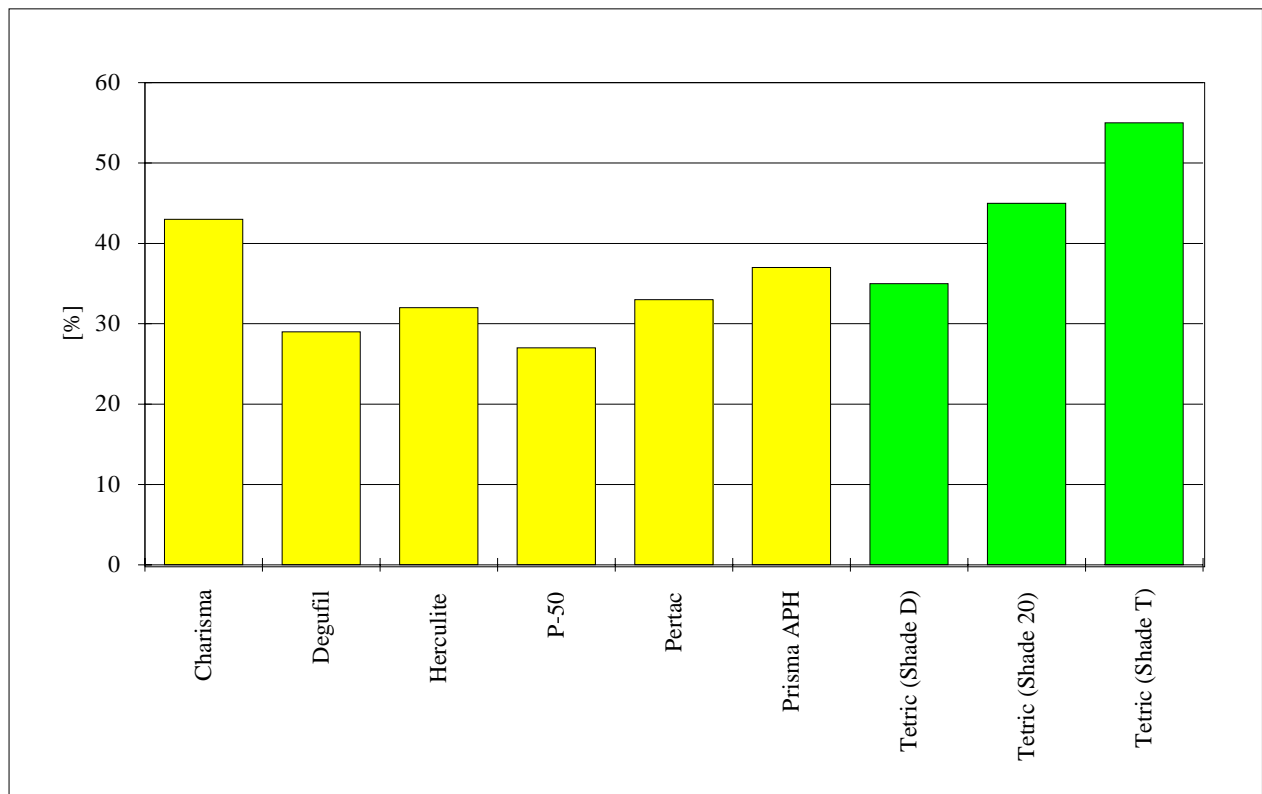


White and Seghi, 1995

Conclusion: The authors recommend composites with a high degree of fracture resistance for restorations involving incisal edges and cusps.

4.2. *Optical Properties*

Translucency of Light Shades

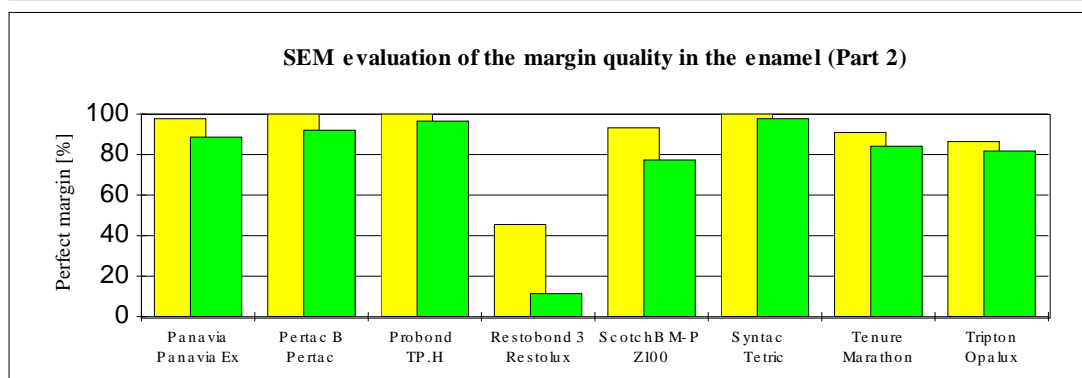
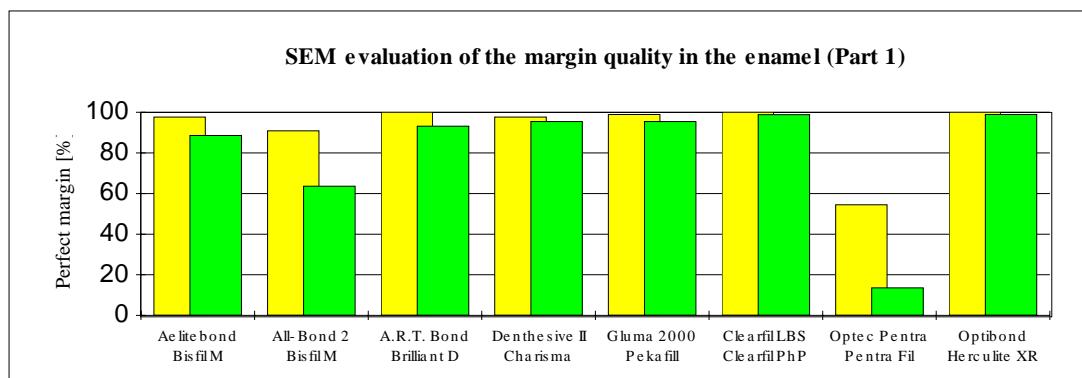
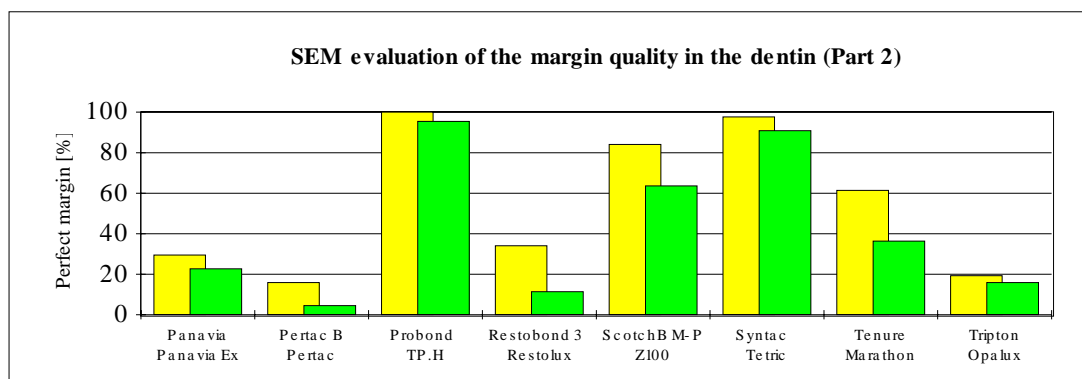
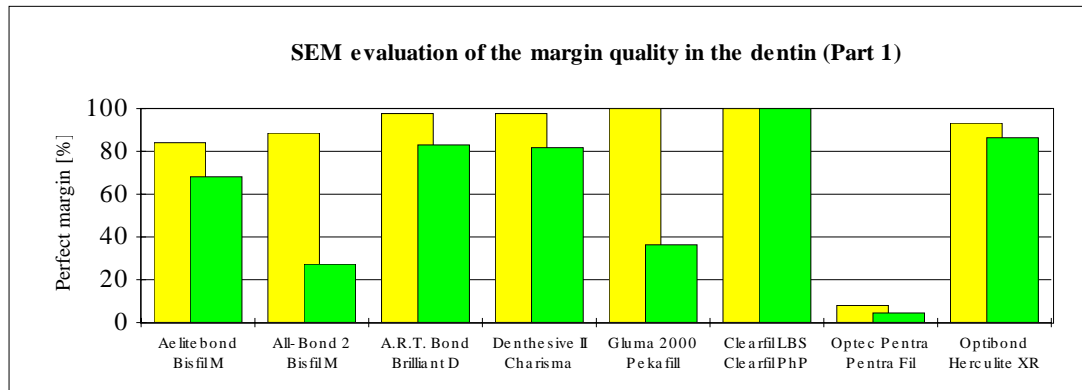


Vivadent R&D, Schaan

Conclusion: With Tetric dentists can restore the natural aesthetics of teeth by replacing missing dental tissue with a restorative demonstrating tooth-like translucency.

4.3. Marginal Adaptation of Composite-Adhesive Systems in Dentin and Enamel

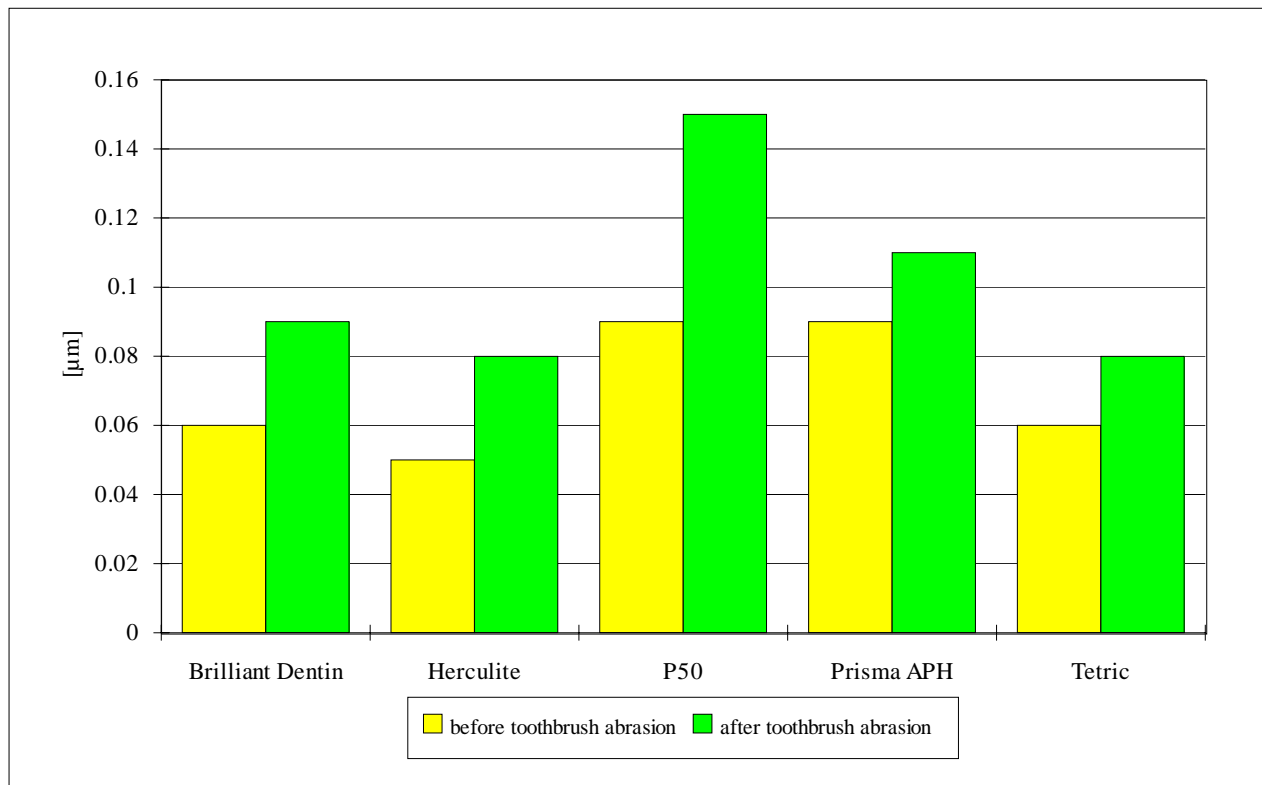
Krejci and Lutz, 1995



before thermocycling after thermocycling

Conclusion: A tight marginal seal in dentin and enamel can be achieved with Tetric and Syntac. The bond remains intact, even during loading. The outstanding marginal adaptation prevents marginal discoloration and secondary caries.

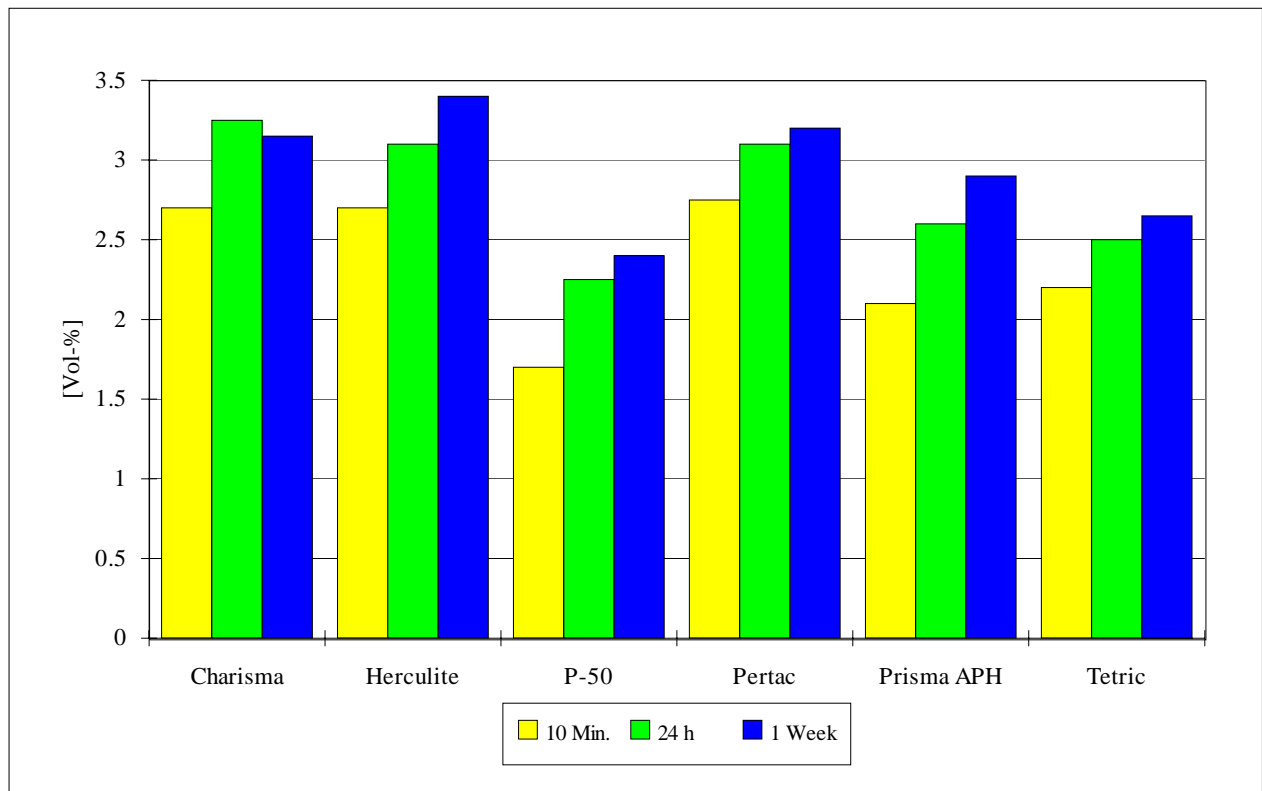
4.4. Surface Characteristics R_a



In vitro clinic, Vivadent, Schaan

Conclusion: Tetric demonstrates a smoother surface compared with that of other hybrid composites. This surface is only slightly roughened by toothbrush abrasion.

4.5. Polymerization Shrinkage

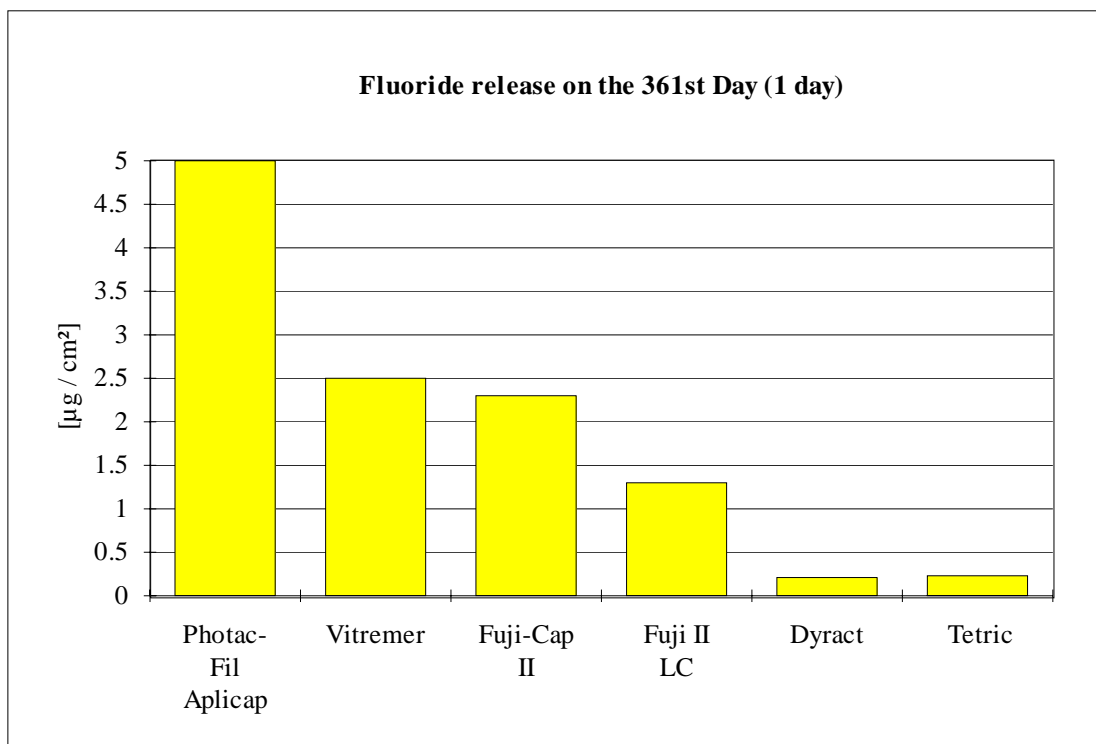
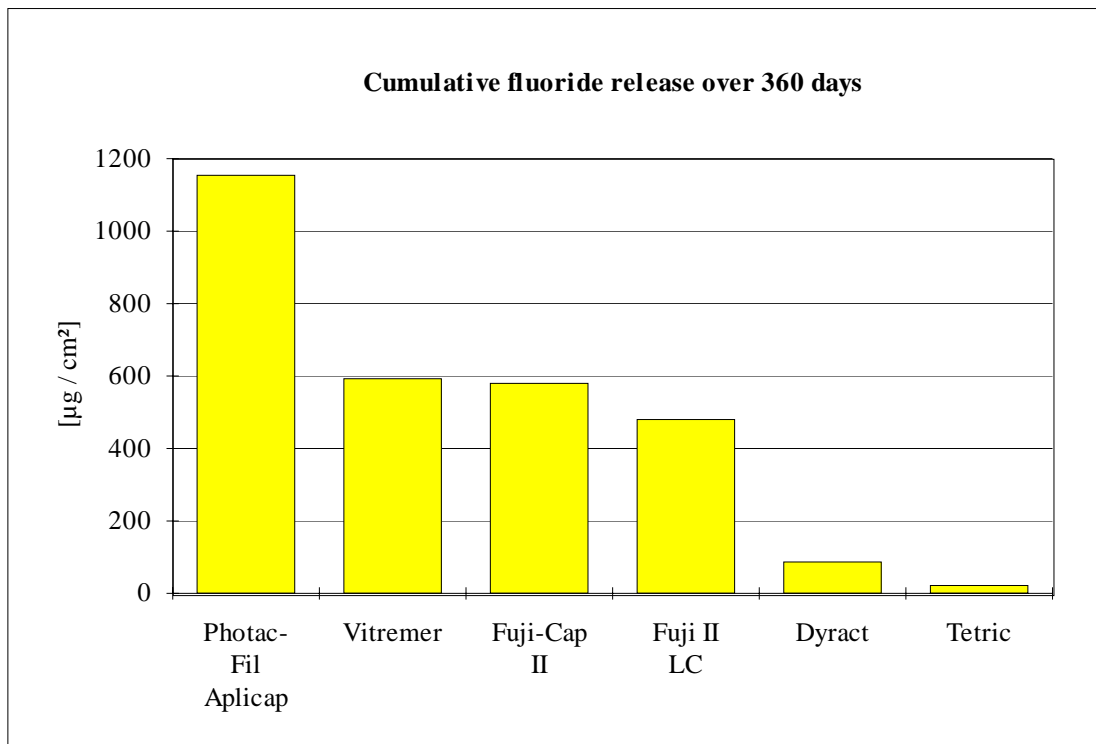


Vivadent R&D, Schaan

Conclusion: Tetric demonstrates a low degree of polymerization shrinkage. Hence, less stress is produced at the cavity margins, which in turn, has a favourable effect on the marginal adaptation.

4.6. Fluoride Release

4.6.1. Fluoride Release in a Test Solution



Aboush et al., 1995

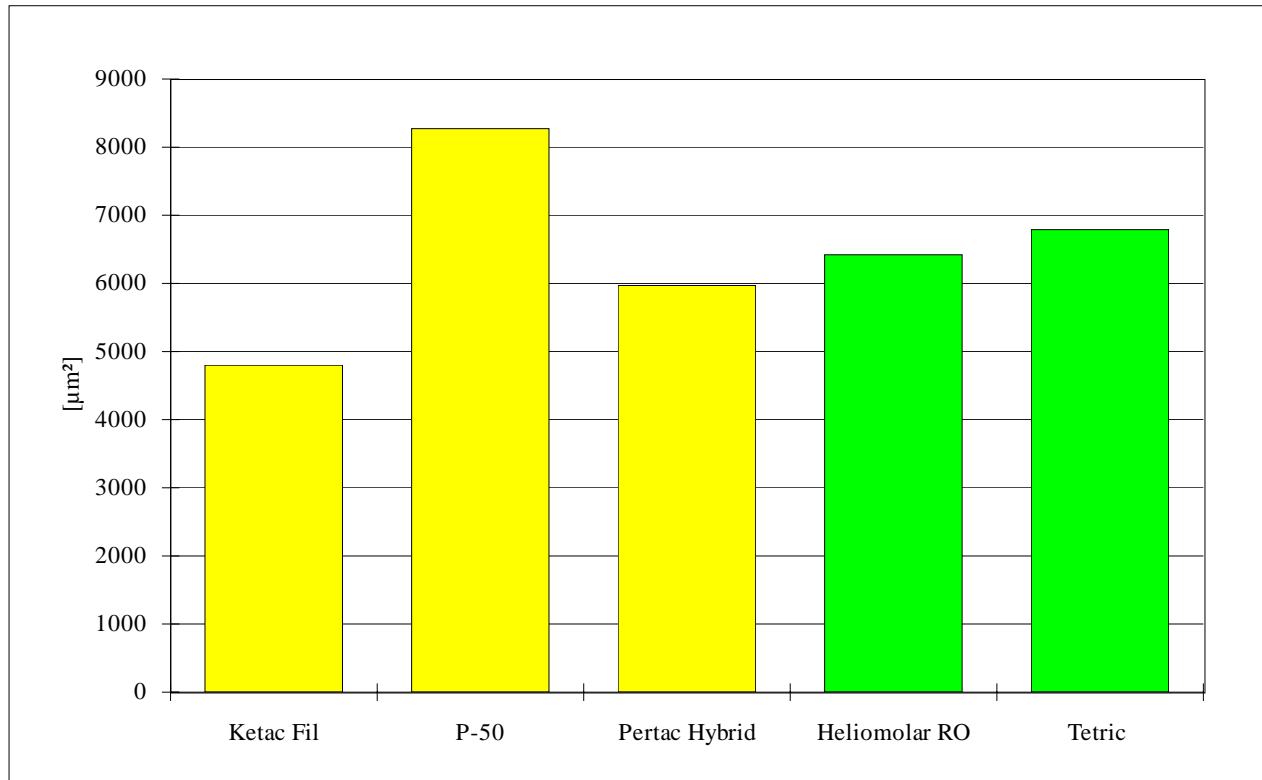
Conclusion: Although Tetric releases fluoride over an extended period, the fluoride release is substantially lower than that of glass ionomer cements.

Surprisingly, Tetric releases more fluoride in one year than does Dyract (Compomer).

4.6.2. Caries Inhibition Assisted by Restoratives Releasing Fluoride

In this in vitro study, the effect of different restorative materials on the demineralization of dentin was examined with artificial caries.

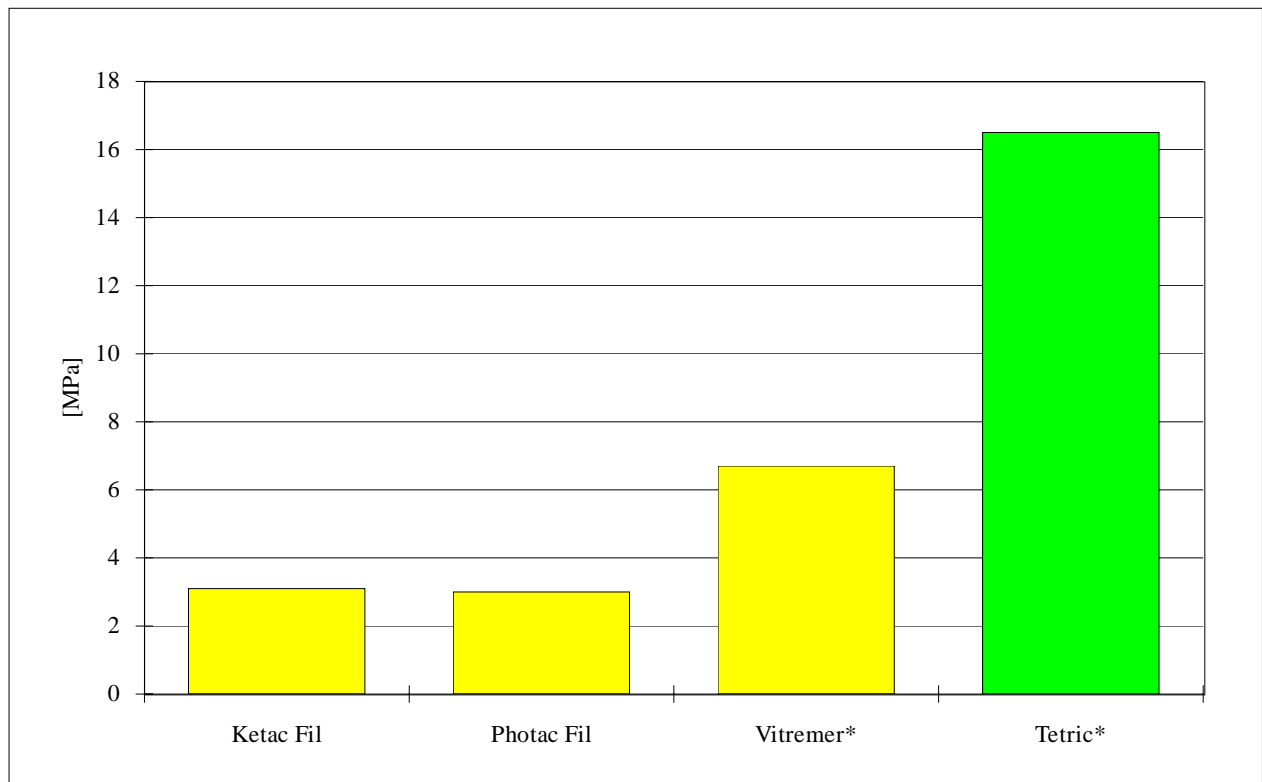
Demineralization 100 μm of the restoration margin in the dentin



Parpia and Donly, 1995

Conclusion: Glass ionomer cements and composites that release fluoride can inhibit secondary caries.

4.6.3. Shear Bond Strength of Restoratives Releasing Fluoride

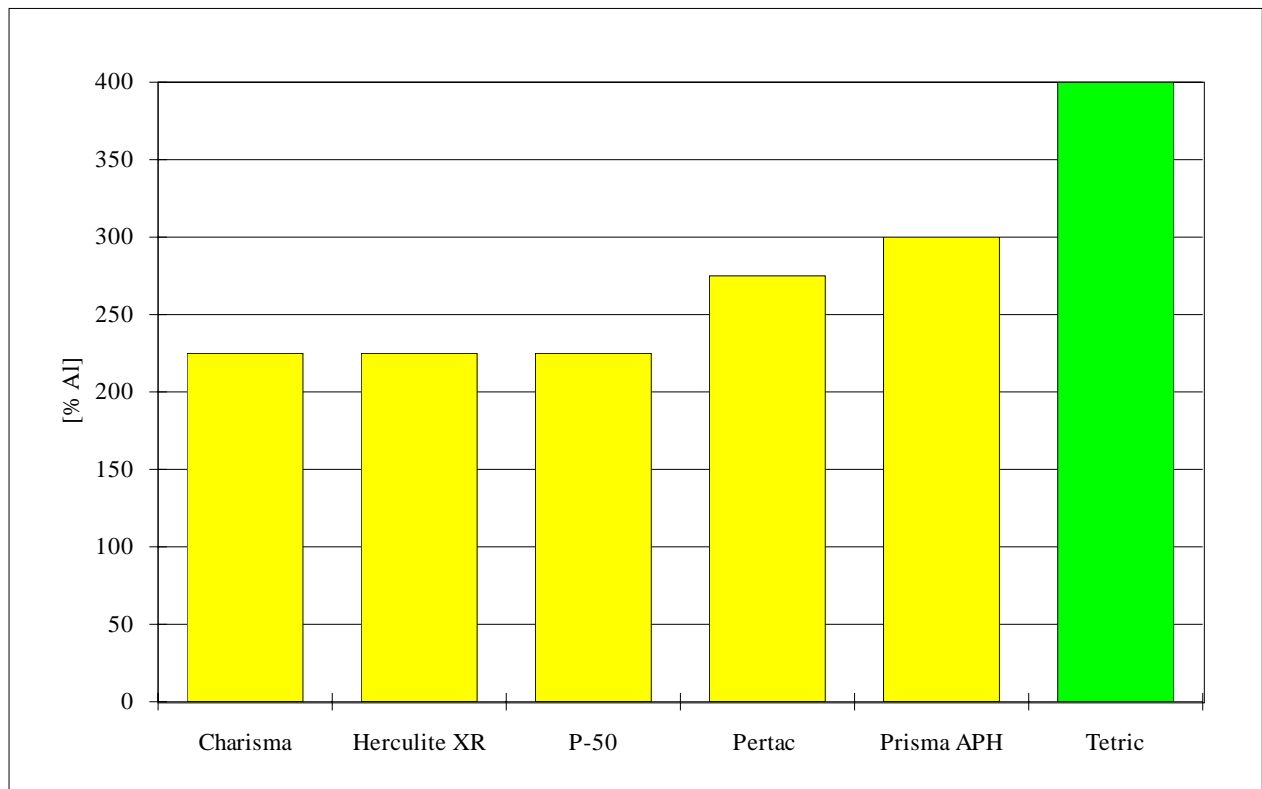


Frutts et al., 1995

* with dentin bonding agent

Conclusion: Among the restoratives examined, Tetric demonstrated the best bond with dentin.

4.7. Radiopacity



Vivadent R&D, Schaan

Conclusion: Tetric demonstrates the highest radiopacity. As a result, restorations can be easily and accurately evaluated.

5. Clinical Studies

Head of study: Krejci I, Besek M, Lutz F

Institution: University of Zurich, Switzerland

Title: Clinical and SEM study of Tetric resin composite in posterior teeth

Objective: Clinical evaluation of Tetric, in conjunction with Syntac, as a direct restorative for box-shaped posterior restorations.

Study: "Thirty-nine composite conventional posterior composite fillings were placed according to the three-sited light-curing technique using Tetric, a fine hybrid composite material, and Syntac, a dentin adhesive. Six and twelve months later, the restorations were clinically evaluated using macrophotographs. A quantitative marginal analysis was also done immediately after placing the restorations and at the two recall intervals using a replica technique and an SEM."

Results:

Recall after 6 months (n=37)	A		B		C	
	n	%	n	%	n	%
Shade match*	36	97	1	3		
Margin discolouration*	36	97	1	3		
Anatomic shape**	37	100				
Surface porosity**	30	81	7	19		
Interproximal contacts**	36	97	1	3		
Secondary caries**	37	100				
Postoperative sensitivity**	36	97	1	3		
Breakage**	37	100				
Recall after 12 months (n=33)	A		B		C	
	n	%	n	%	n	%
Shade match*	32	97	1	3		
Margin discolouration*	32	97	1	3		
Anatomic shape**	32	97	1	3		
Surface porosity**	33	100				
Interproximal contacts**	25	76	8	24		
Secondary caries**	33	100				
Postoperative sensitivity**	33	100				
Breakage**	33	100				
	33	100				
* Evaluation with macrophotography			A = excellent to good			
** Clinical evaluation			B = satisfactory			
			C = unsatisfactory			

Conclusion: Ninety-eight to one hundred percent of the composite posterior restorations tested rated "A" in five categories of direct evaluation. The SEM evaluation of the marginal adaptation showed 90% "continuous margins." Although only 12-month results are available, the material and the working technique are promising.

Publications: Krejci et al., 1994
Krejci et al., 1995

- Head of study:** Lohner C, Hickel R, Kunzelmann KH
- Institution:** University of Munich, Germany
- Title:** Clinical study of "light-curing glass ionomer cements" and compomer and composite restorations
- Objective:** Comparison of "light-curing glass ionomer cements" with compomer and composite Class V restorations in a prospective clinical study.
- Study:** A total of 37 patients received 198 cervical restorations. Fuji II LC (51), Photac Fil (31), Dyract (83) and Tetric/Syntac (33) were used according to the instructions of the manufacturer, but without a rubber dam in all cases. Each patient received four restorations of the same material. The cases were documented with photos and models. Depending on the clinical situation, the sites were cleaned or a cavity prepared. The defects were classified as "cervical and abrasion cavities" (69), "inadequate restorations" (69), and "caries" (60). The enamel margin was bevelled for Tetric/Syntac. The same dental professional placed all the restorations. Recall examinations took place six to twelve months after the restoration was placed, using modified USPHS criteria.
- Results:** During the observation period, 2 Photac Fil ("6 %"), 2 Fuji II LC ("4 %") and 3 Dyract restorations ("4 %") were lost. The clinical situation for Tetric/Syntac remained unchanged. The criteria of "anatomic shape", "marginal discoloration of dentin", and "marginal discoloration of enamel" were used to establish the following order for the restorative materials: Tetric > Dyract > Fuji II LC > Photac Fil.
- Conclusion:** On the basis of the first recall examinations, Dyract and Tetric/Syntac seem to be superior to "light-curing glass ionomer cements" when used for Class V cavities. Dyract is easier to handle than Tetric, while Tetric is easier to polish. Tetric is also more stable with regard to "anatomic form".
- Publications:** Abstract, DGZ 1995, Berlin

Head of study: Dr. R. Christensen, Clinical Research Associates (CRA)

Institution: CRA, Provo, Utah, USA

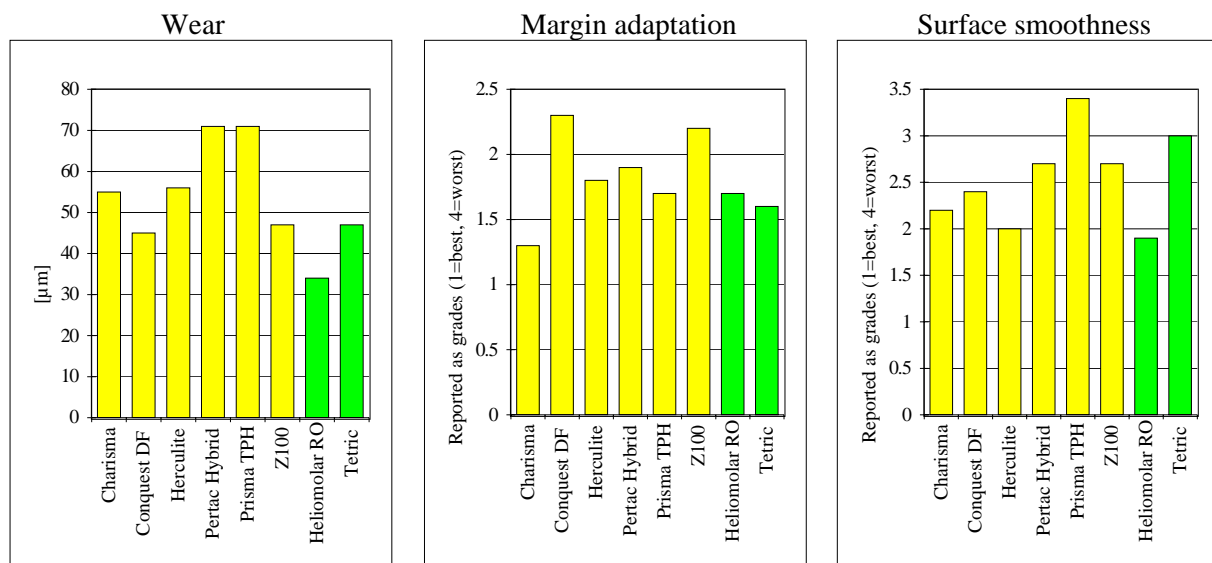
Title: Restorative resins, new materials

Objective: Clinical comparison of six new composite materials with two time-proven composites in Class II cavities.

Study: Fifty-two Class II restorations were placed with each material. The restorations were placed by different dentists. The restorations were evaluated according to (1) direct clinical observation, (2) indirect observation (SEM, slides: margin adaptation, surface smoothness, breakage). Wear was measured quantitatively.

Results: The restoratives examined did not differ with regard to the following characteristics: shade match, margin discoloration, interproximal contacts, postoperative sensitivity, need for endodontic treatment, secondary caries, and breakage.

The restoratives differed with regard to the following characteristics:



Conclusion: "Statistically at one year, the six new generation resin formulations compared to time-proven Heliomolar RO & Herculite show very few differences. In wear Conquest DF, Z100, and Tetric are the same as Heliomolar RO which has been shown to have very low wear over time. In margin adaptation, Charisma is the superior material. These data indicate the six new resins show excellent promise as Class II restorative materials." The study is still in progress.

Publications: CRA Newsletter, October 1993
CRA Newsletter, November 1994
Hein et al., 1995

Head of study: Wilson NHF

Institution: University of Manchester, England

Title: Clinical testing of Tetric for the direct restoration of large Class II cavities

Objective:

- Evaluation of the working properties of Tetric under clinical conditions
- Evaluation of the Tetric restorations according to direct (clinical) and indirect criteria over a period of at least another four years

Results: Forty-five Tetric restorations were placed. The working properties were determined as excellent. The study has been in progress for 1.5 years. As nothing has been published about the study to date, the internal report may only be quoted as follows: "On the basis of the findings reported, the 18-month performance of Tetric in moderate to large-sized Class II preparations in premolar and first and second permanent molar teeth in adult patients is considered to be most promising."

Head of study: Suzuki S

Institution: University of Alabama, Birmingham, USA

Title: Clinical study of Tetric as a universal composite

Objective: Evaluation of the clinical performance of Tetric in anterior and posterior teeth over a period of three years

Results: Forty-three Tetric restorations were placed, ten in premolars and thirty-three in molars. Sixty percent of the restorations were placed in Class II cavities. Tetric is described as a composite with outstanding surface characteristics. It polishes easily, demonstrates ideal shade matching ability, and is highly resistant to fractures within the restoration as well as in the margin.

Publications: Leinfelder, 1995

Head of study: Vreven J

Institution: University of Brussels, Belgium

Title: Clinical study of Tetric as an anterior composite

Objective: Evaluation of the clinical performance of Tetric in anterior teeth over a period of at least two years

Study: Thirty patients will participate in the study. Tetric will be compared with two other restoratives used on the same patient. As a result, only patients requiring at least three comparable restorations may participate in the study.

Status: Some of the restorations still have to be placed.

6. Toxicological Data

The following examinations are necessary for evaluating the biocompatibility of dental materials:

- Acute oral toxicity: The patient accidentally swallows the entire amount of the adhesive or restorative material
- Local tolerance with the surrounding tissue that comes in contact with the material
- Potential sensitizing reactions
- Mutagenic potential of eluted, low-molecular components

6.1. Acute Oral Toxicity

The acute oral toxicity is determined from the relationship between the dose and the effect, tested on rodents. The lethal dose (LD₅₀ value) was established as the measure for the toxicological effect.

The LD₅₀ value for the uncured formula can be established with the experimental data:

Tetric > 5000 mg / kg

ACUTE TOXICOLOGICAL RISK OF TETRIC CAN THUS BE EXCLUDED.

6.2. Primary Local Irritation

The uncured material can be considered inert. It is virtually identical to another Vivadent product, with the exception of the inert fillers. This product produced slight irritation in an eye irritation test [1]. The examination was not repeated because of animal protection reasons. The results of the previous examination were transferred to Tetric.

6.3. Sensitization

Sensitization means that heightened sensitivity or allergic reactions are induced to the chemical substance. The sensitizing potential of a chemical substance was tested on the skin of albino guinea pigs [2].

NO ALLERGIC REACTIONS TO TETRIC WERE OBSERVED UNDER THE GIVEN TEST CONDITIONS. TETRIC CAN THUS BE CONSIDERED NON-SENSITIZING.

6.4. *Mutagenicity*

Mutagenicity of a substance can be easily and reliably determined with a bacterial test (Ames Test, [3]). Tetric was examined with Salmonella thyphimurium strains (TA 1535, TA 1537, TA 1538, TA 98 and TA 100) [4].

NO INCREASE IN THE MUTATION RATE WAS DETERMINED IN AN AMES TEST CONDUCTED UNDER THE SELECTED EXPERIMENTAL CONDITIONS. IN THESE TESTS, TETRIC WAS DEMONSTRATED TO BE NON-MUTAGENIC.

6.5. *Cytotoxicity*

The toxicity of eluted, low-molecular substances can be determined with cultivated cells of mammals. The cytotoxicity of the cured material was examined on the basis of an Agar overlay test. The results show that Tetric does not release toxic components and that the material does not demonstrate a cytotoxic effect. [5].

NO CYTOTOXICITY WAS DETERMINED FOR TETRIC.

6.6. *Chronic Exposure*

Chronic toxicity may be possible as result of constant release of soluble substances from the restorative into the body. Hence, an elution test [6] was carried out according to Swiss Standard 19800. Measurements after the first week demonstrated a total migration of 2.5 $\mu\text{g}/\text{cm}^2 \cdot \text{d}$, after four weeks 0.56 $\mu\text{g}/\text{cm}^2 \cdot \text{d}$, and after four months only 0.1 $\mu\text{g}/\text{cm}^2 \cdot \text{d}$.

ON THE BASIS OF THE LOW AMOUNTS OF SOLUBLE SUBSTANCES RELEASED, DEMONSTRATING PRACTICALLY NO ACUTE TOXICITY, NO CHRONIC HEALTH RISK IS TO BE EXPECTED.

SUMMARY:

ON THE BASIS OF THE AVAILABLE DATA, AN ACUTE OR CHRONIC HEALTH RISK TO THE PATIENT CAN BE RULED OUT ALMOST ENTIRELY IF TETRIC IS CORRECTLY USED.

[1] RCC Project 034604
Primary eye irritation in rabbits with a Vivadent product
August 1984

[2] RCC Project 319915
Contact hypersensitivity to Tetric in albino guinea pigs. Modified Bühler Method
April 23, 1992

-
- [3] Ames BN, Mccann J, Yamasaki E
Methods for detecting carcinogens and mutagens with the Salmonella / mammalian-microsome mutagenicity test
Mutation Research 31 (1975), 347-364
- [4] CCR Project 314908
Salmonella thyphimurium reverse mutation assay with Tetric
December 17, 1992
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