

Tetric® N-Collection

A complete nano-optimized restorative system



Tetric® N-Collection

Tetric® N-Ceram | Tetric® N-Flow | N-Etch | Tetric® N-Bond | Tetric® N-Bond Self-Etch

Scientific Documentation

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1. Introduction

Composite materials became available to dentistry in the sixties of the last century [1]. In the beginning, they were mainly used in the anterior region, where the colour of amalgam was esthetically unsatisfying. After effective dentin bonding systems became available approximately in 1992, composites were widely used as universal filling materials. The growing demand for invisible restorations has led to an increase in the demand for composite materials and a decrease in the use of amalgam, as Figure 1 illustrates.

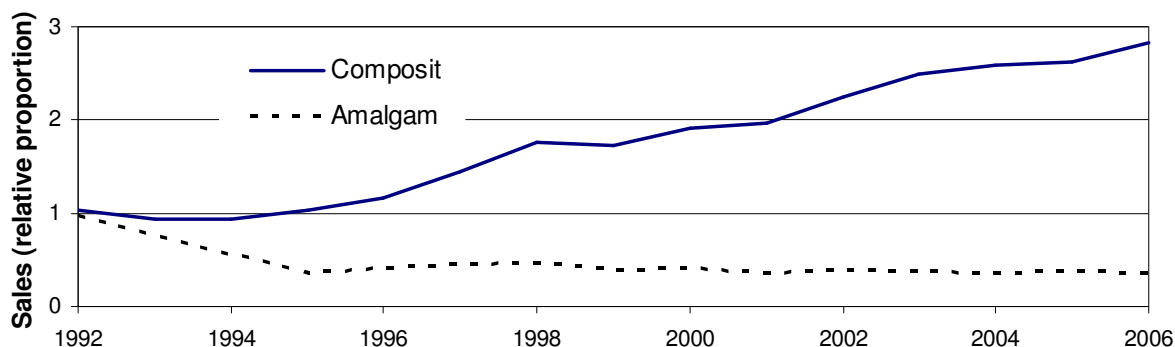


Fig. 1: Sales of amalgam and composites in Germany from 1992 to 2006. Source: GfK Healthcare, Nuremberg, Germany

The trend towards composites was accelerated in the nineties due to public concerns about health risks from amalgam fillings. The terms “amalgam replacement material” [2; 3] or “amalgam alternatives” [4], which initially were often used for composites, result from this development. Today, the discussion: “amalgam or composite” is still ongoing. Nevertheless, it is becoming generally accepted that adhesive composite restorations are the first choice for direct restorations.

Not only the desire of the patient for invisible restorations and the poor acceptance of amalgam have contributed to the success story of dental composites. This development also reflects the continuous improvement of dental restorative materials. Nowadays, clinically reliable enamel/dentin adhesives and composite materials with the required physical properties, esthetic possibilities and easy handling properties are available. In the following section, the development of composite materials is briefly outlined.

1.1 Composite materials

1.1.1 Historical development

The first step in the development of current composite materials was made in 1962 with the synthesis of the new monomer Bis-GMA, which was filled with milled quartz [1]. At that time, only chemically-curing two-component resin-based materials were available. In 1970, one of the first reports on a UV-curable fissure sealant appeared [5]. UV-curing was not a successful strategy because of the short penetration depth of UV light, limiting increment thickness and moreover the health hazards linked to UV exposure. At the end of the seventies, the first reports of dental filling materials cured with visible light were published [6]. Only shortly later, in 1980, Ivoclar Vivadent entered the light-curing materials market with the microfilled composite Heliolit.

1.1.2 Filler technology

The first macrofilled composites were clinically not successful because of their inadequate surface properties and poor wear resistance [7]. In 1974, a patent was granted to Ivoclar Vivadent on a composite employing microfillers [8]. Those microfilled composites brought about the breakthrough as they were the first materials to be sufficiently wear resistant and maintained an acceptable surface quality. However, microfilled composites could not overcome two problems. Firstly, the microfillers strongly increased the viscosity of a composite due to their high specific surface area; thus, the content of microfillers is limited. Therefore, microfilled composites exhibit high polymerization shrinkage. Secondly, inorganic microfillers do not reinforce a composite material as well as macrofillers, which results in low flexural strength and a low flexural modulus. These disadvantages, in particular the shrinkage, can largely be overcome by preparing a microfilled composite which is, after polymerization, milled to a grain size that can be employed as filler in a dental material. Such fillers are called “prepolymers” or “isofillers.” With IsoCap [9; 10] and Isosit [11], Ivoclar Vivadent materials were among the first to employ this technology. Heliomolar has so far been the most successful composite of this group.

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

Microfilled composites typically exhibit a better wear resistance than hybrid composites. Indeed, it was found that smaller filler particles resulted in less wear [12]. Previously, only spherical silicon dioxide and mixed oxide fillers were available, which had homogeneous particle sizes in the micro- (< 1 μm) or nano range (< 100 nm) (see Figure 2a and b). Such fillers were either produced in a pyrogenic or a sol-gel process, where particles grew to the desired size during the manufacturing process.

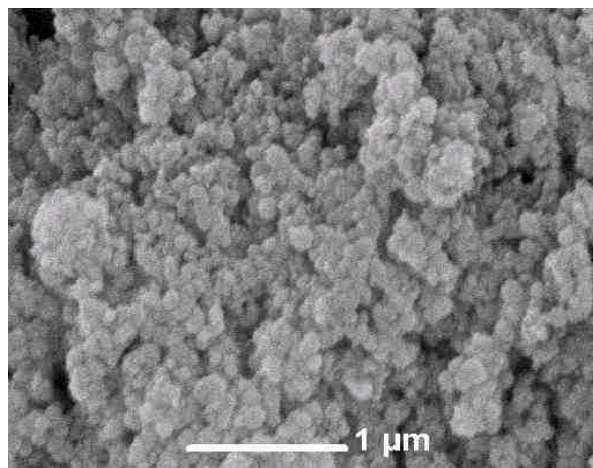


Fig. 2a: Silicon dioxide microfiller. The mean particle size is 40 nm. Scanning electron microscopy (SEM) image.

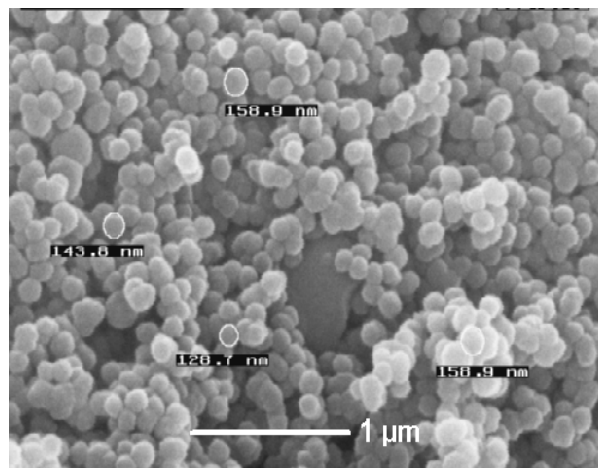


Fig. 2b: Mixed oxide filler. The mean particle size is 160 nm. Scanning electron microscopy (SEM) image.

In contrast, the glass fillers typically used in hybrid composites are made by means of a milling process. Only recent technical progress has allowed to obtain microfillers through milling (see Figure 3a and b).

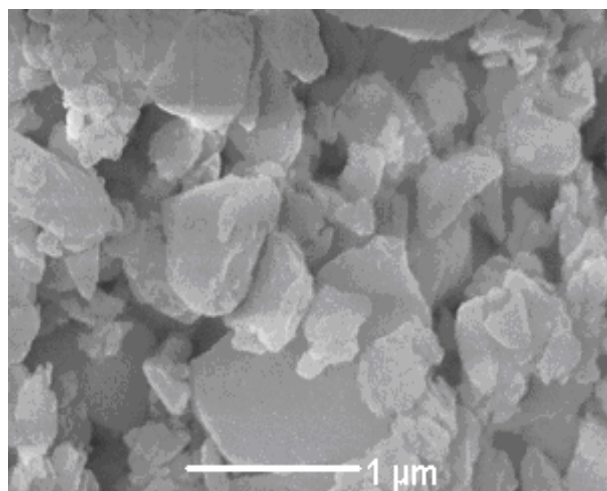
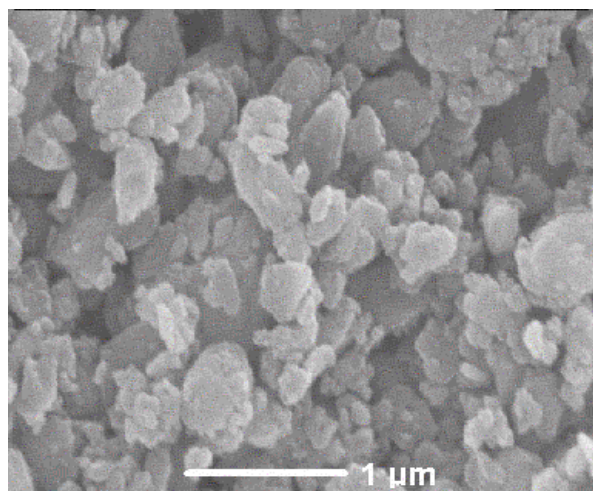


Fig. 3a: Barium aluminium silicate glass microfiller. The mean particle size is 0.5 µm. Scanning electron microscopy (SEM) image.

Fig. 3b: Barium aluminium silicate glass filler. The mean particle size is 0.7 µm. Scanning electron microscopy (SEM) image.

By using a glass microfiller with a mean particle size of 0.6 µm, the wear of Tetric N-Ceram could be improved in comparison to the predecessor product Tetric Ceram.

1.1.3 Radiopacity

Radiopacity refers to the relative inability of electromagnetic radiation, particularly X-rays, to pass through a particular material. Radiopaque materials appear opaque white in the radiographic image.

Posterior restorations must demonstrate adequate radiopacity to permit the detection of secondary caries, or imperfections like air bubbles. The minimum radiopacity of restorative materials should be similar to the radiopacity of dental enamel (i.e. 200 % of aluminium (%Al)) [13; 14]. Nevertheless, only a few composite restoratives demonstrate radiopacity higher than 250 % Al.

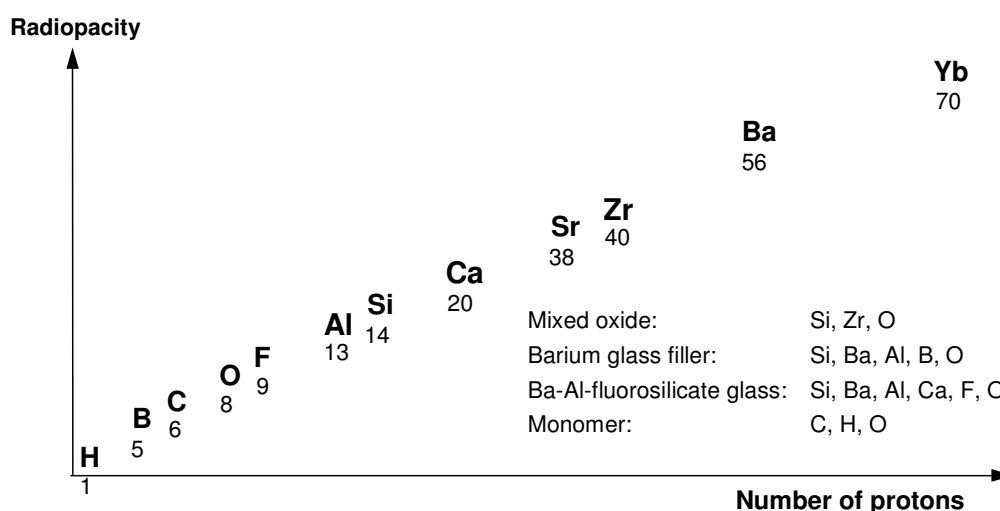


Fig. 4: Radiopacity of elements contained in composite materials.

The radiopacity of a material correlates to its chemical composition. Elements with a high number of protons are more radiopaque than elements with low numbers of protons in the nucleus (see Figure 4).

Composite monomers consist of hydrogen, carbon and oxygen and are thus barely radiopaque. Flowable composites typically have a higher monomer content than highly viscous materials, thus they are typically also less radiopaque. Hence, to increase the radiopacity of composite filling materials, chemical elements with very high radiopacity have to be added. Most manufacturers employ barium aluminium silicate glasses as fillers. In contrast, Ivoclar Vivadent uses ytterbium trifluoride, which provides composite materials such as Tetric N-Ceram with an unmatched radiopacity and, simultaneously, fluoride release.

1.1.4 Tetric N-Ceram – The nano-optimized successor of Tetric Ceram

Ivoclar Vivadent has been at the leading edge of composite development. Many innovations in composite development, such as the pre-polymers and the radiopaque filler ytterbium trifluoride, have been brought to dentistry by Ivoclar Vivadent researchers. What once was an innovation is now proven technology. The competence in composites that Ivoclar Vivadent has gained during recent decades has resulted in the development of Tetric N-Ceram.

Tetric N-Ceram comprises features of nanotechnology. “Nano additives” have been incorporated in a targeted fashion. The rheological modifier contained in Tetric N-Ceram is an example of such a nano additive. As in Tetric Ceram, this modifier is responsible for the material’s viscosity and good pliability. Furthermore, organic pigments, which are covalently bonded to silicon dioxide particles in the nanoscale range, enable an outstanding colour match of Tetric N-Ceram with the natural tooth structure.

1.2 Flowables and adhesives

1.2.1 Tetric N-Flow, Tetric N-Bond, N-Etch and Tetric N-Bond Self-Etch – Ideal supplements to form a complete restorative system

With Tetric N-Flow, Ivoclar Vivadent offers a flowable composite that is exactly matched to Tetric N-Ceram with respect to the shade and the nano-optimized technology. This facilitates the predictability of the esthetic outcome.

The nano-filled, light-cured, single-component total-etch adhesive Tetric N-Bond complements the Tetric N-Collection of products with a suitable bonding solution. Its outstanding clinical performance has been demonstrated for many years. N-Etch, the 37% phosphoric acid gel is the best partner for Tetric N-Bond.

Recently, Tetric N-Bond Self-Etch has been added to the Tetric N-Collection of products. It provides an all-in-one solution including both etching and bonding steps and renders restorative therapy even faster and easier.



Fig. 5: The convenient “VivaPen”. Both Tetric N-Bond and Tetric N-Bond Self-Etch are available in the “VivaPen” delivery form which ensures fast and easy direct application.

Moreover, both Tetric N-Bond and Tetric N-Bond Self-Etch are not only available in bottles, but also in the convenient “VivaPen” delivery form. The VivaPen simplifies the application of the product, as it does not have to be dispensed onto a mixing pad. The VivaPen allows the required amount of adhesive to be applied exactly where needed.

1.2.2 Technological challenges in the development of self-etching adhesives

In multi-component adhesives, individual components are responsible for different effects. One-step products have to contain all active substances in one “bottle”. Combining several steps which comprise often converse or differing working conditions is a technological challenge. In particular, the following two problems have to be overcome:

Solubility of monomers

Multi-step systems employ either phosphoric acid or an acidic primer solution for etching. Subsequently, a more hydrophobic bonding solution is applied. In one-component self-etching adhesives, the acid and the water necessary for etching must be mixed with the less hydrophilic monomers of the bonding agent. For this reason, some all-in-one products use a water/organic solvent, e.g., acetone, to dissolve the monomers. Such products may suffer from phase separation upon evaporation of the organic solvent [15]. This process is nicely illustrated in Figure 6: Upon dispensing a drop of material onto the pad, acetone starts to evaporate. Separation of the water and the organic phase occurs which becomes obvious by the formation of water drops. This effect is particularly detrimental to the product if it is not immediately used upon dispensing.



Fig. 6: Phase separation of a water-acetone mixture.

Hydrolytic stability of methacrylate monomers

Commonly used dental methacrylate monomers are not stable under acidic or alkaline conditions, because they contain an ester bond (see Figure 7). Hydroxyethyl methacrylate (HEMA), a typical hydrophilic monomer employed in dental adhesives, is such an example. Under acidic conditions, it is hydrolyzed according to the reaction shown in Figure 8 to methacrylic acid and ethylene glycol.

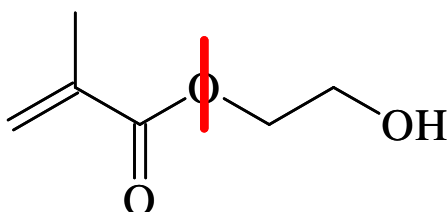


Fig. 7: Hydroxyethyl methacrylate (HEMA). The mark shows the site of hydrolytic cleavage of the molecule under acidic conditions.

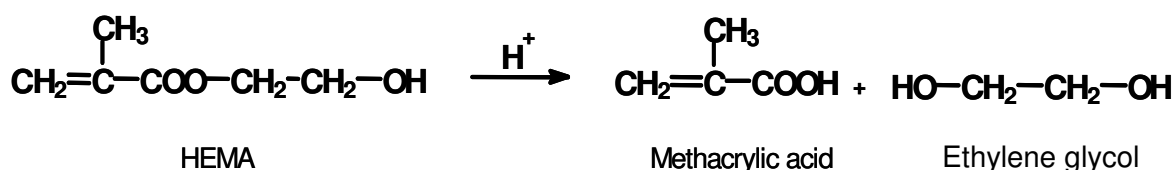


Fig. 8: Hydrolysis of hydroxyethyl methacrylate (HEMA).

A study compared the hydrolytic stability of methacrylates with the one of methacrylamides at highly acidic conditions (pH 0.94) and 37°C. The methacrylate HEMA decomposes nearly completely within two weeks under these conditions. In contrast, methacrylamides show an elevated hydrolytic stability. This makes them promising monomers for self-etching dental adhesives [16]. Analyses done at Ivoclar Vivadent were in accordance with these results: Methacrylamides were stable for weeks, whereas methacrylates decomposed rapidly (see Figure 9).

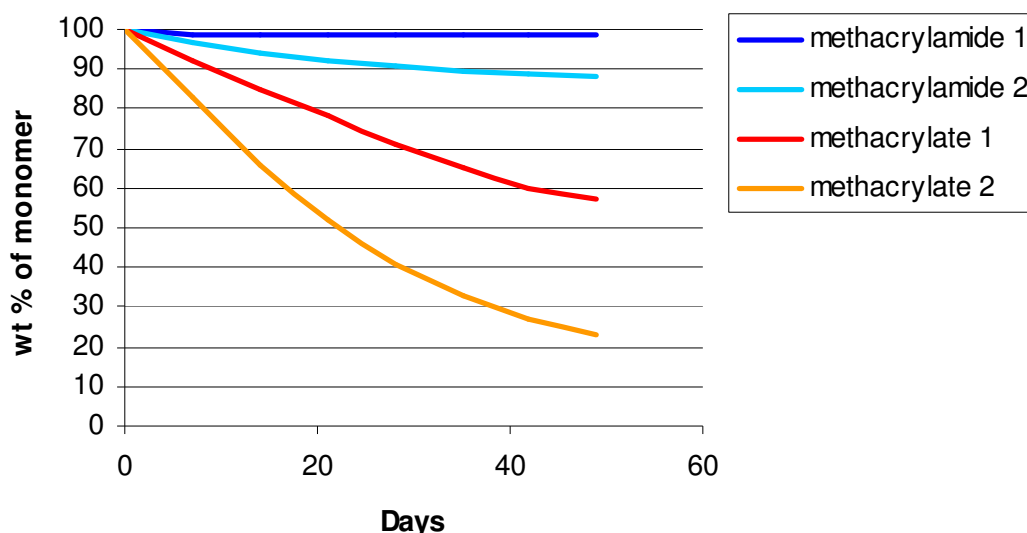


Fig. 9: Hydrolytic stability of methacrylamides in comparison to methacrylates.

Investigation: R&D Ivoclar Vivadent, Schaan, Liechtenstein

Furthermore, recent research suggests that hydrolysis within the dentin-adhesive-composite interfaces may even occur after application and polymerization of the product. An *in-vitro* investigation compared the marginal integrity of Class-V restorations prepared with all-in-one self-etching adhesives versus multi-bottle adhesives after thermocycling and storage in water. The results impressively demonstrated that after the first thermocycling period, all adhesives exhibited acceptable marginal quality. However, when specimens were stored in water for one year and thermocycled again, some all-in-one products exhibited a substantial decrease in marginal quality [17]. Another study which also examined the bonding strength of self-etch adhesives under thermocycling conditions showed that the micro tensile bond strength was correlated to the hydrolytic stability of the (calcium salt of the) monomer [18]. Thus, prevention of hydrolysis is essential for the stability and the clinical performance of self-etch adhesives.

Manufacturers of self-etching adhesives have come up with different solutions to reduce or prevent hydrolysis:

- The acid monomers of the primer and water are mixed just before use.
- The product has to be refrigerated to retard hydrolysis.

However, such measures only partly solve the problem of lacking hydrolytic stability. For two-component products, errors during mixing may compromise the performance of a product. Incorrect storage conditions of products which have to be refrigerated on their way from the manufacturer to the customer may reduce the shelf life of the products.

At Ivoclar Vivadent, researchers have accepted and successfully resolved the challenge to develop hydrolytically stable monomers.

1.2.3 Hydrolytically stable monomers from Ivoclar Vivadent

Ivoclar Vivadent has consistently pursued the goal of developing hydrolytically stable monomers for dental materials. Tetric N-Bond Self-Etch exclusively contains those innovative substances. Table 1 shows the chemical structures of hydrolytically stable Ivoclar Vivadent monomers in comparison with hydrolytically unstable monomers used in competitor products.

Table 1: Hydrolytically stable vs. unstable monomers. Marks indicate the site of hydrolytic cleavage.

Function	Tetric N-Bond Self-Etch	Examples of competitor's monomers with indication of instable bond
cross-linking monomer		
acidic monomer with affinity to calcium		
hydrophilic wetting monomer		

2. Technical Data

Tetric N-Ceram, Tetric N-Flow

Standard composition	Tetric N-Ceram (wt%)	Tetric N-Flow (wt%)
Urethane dimethacrylate, Bis-GMA	15.0	27.8
Ethoxylated Bis-EMA	3.8	-
Triethyleneglycol dimethacrylate	-	7.3
Barium glass, ytterbium trifluoride, mixed oxide, silicon dioxide	63.5	63.8
Prepolymers	17.0	-
Additives, stabilizers, catalysts, pigments	0.7	1.1

Physical properties	Tetric N-Ceram	Tetric N-Flow
Flexural strength (MPa)	130	110
Modulus of elasticity (MPa)	10,800	5,300
Compressive strength (MPa)	267	230
Vickers hardness (MPa)	630	350
Water absorption ($\mu\text{g}\cdot\text{mm}^{-3}$)	24	24
Water solubility ($\mu\text{g}\cdot\text{mm}^{-3}$)	< 1	1
Radiopacity (%Al)	400	280
Depth of cure (mm)	> 1.5	> 2
Transparency (%), depending on shade	6.5 - 20	13 - 15
Density ($\text{g}\cdot\text{cm}^{-3}$)	2.16	1.83

Tetric N-Bond, Tetric N-Bond Self-Etch

Standard composition	Tetric N-Bond (wt%)	Tetric N-Bond Self-Etch (wt%)
Bis-GMA, urethane dimethacrylate, dimethacrylate, hydroxyethyl methacrylate, phosphonic acid acrylate	80	-
Bis-acrylamide derivative, Bis-methacrylamide dihydrogenphosphate, amino acid acrylamide, hydroxyalkyl methacrylamide	-	60 - 80
Nano-fillers (SiO ₂)	< 1	< 5
Ethanol	< 20	-
Water	-	20 - 30
Initiators and stabilizers	< 2	< 2

Physical properties	Tetric N-Bond	Tetric N-Bond Self-Etch
Shear bond strength on dentin (MPa)	30	35
Shear bond strength on enamel (MPa)	30	26

3. Laboratory Investigations

3.1 Surface gloss

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

Samples of eight different composite materials were prepared according to the instruction of the respective manufacturer. After dry storage at 37°C for 24 hours, the samples were roughened with 320-grit abrasive paper to obtain similar initial roughness for all samples.

Subsequently, the samples were pre-polished with Astropol F and Astropol P discs for 10 seconds each at a standardized pressure of 2 N at 10,000 rpm in conjunction with water cooling. The final polish was accomplished with the Astropol HP discs and interrupted at intervals of 10 seconds to measure the surface gloss using a Novo-Curve gloss meter.

Figure 10 illustrates that Tetric N-Ceram and Tetric N-Flow achieved a surface gloss equivalent to that of the top products of Ivoclar Vivadent, i.e., Tetric EvoCeram and Tetric EvoFlow.

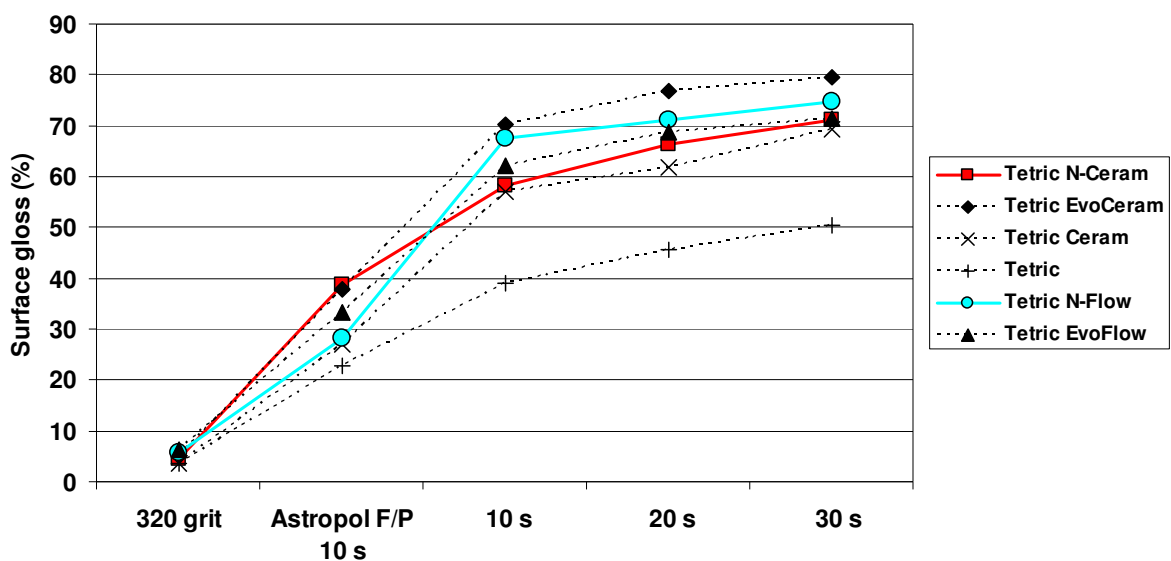


Fig. 10: Surface gloss of various composite materials. The surface gloss of composite materials was determined with a gloss meter after polishing with the three components of the Astropol polishing set (Astropol F, Astropol P and Astropol HP for 10, 20 and 30 seconds).

Investigation: R&D Ivoclar Vivadent, Schaan, Liechtenstein

3.2 Two-body wear

Measuring the wear of dental materials *in vivo* involves lengthy, inaccurate procedures. Even if high-precision impression materials are utilized, the restorations need to be worn for at least 12 to 24 months until the actual wear exceeds the mean variation of measurements. For these reasons, dental materials are subjected to *in-vitro* simulations of mastication processes to estimate their stability under clinical conditions.



Fig. 11: Willytec chewing simulator.

Ivoclar Vivadent uses Willytec chewing simulators (see Figure 11) to measure the wear resistance of restorative materials. Standardized antagonists made of Empress material are used to keep the data variance at a minimum. Plane test samples are subjected to 120,000 masticatory cycles, applying a force of 50 N and a sliding movement of 0.7 mm. No abrasive medium is used (two-body wear). The vertical substance loss and volume loss are measured by means of a 3D laser scanner.

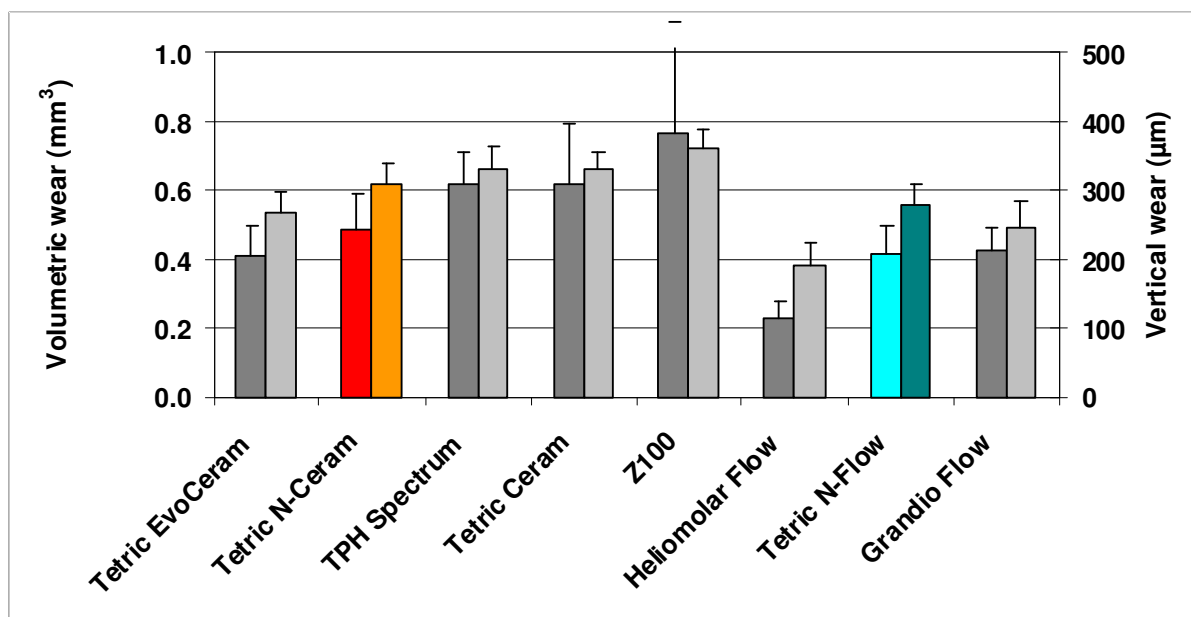


Fig. 12: Volume loss and vertical substance loss of highly viscous and flowable composite materials.

Figure 12 shows the wear parameters (volumetric and vertical wear) for different composite materials. Tetric N-Ceram exhibits improved wear resistance compared to the predecessor product Tetric Ceram. In general, the wear of flowable composites is lower than that of highly filled composites.

3.3 Radiopacity

The radiopacity of dental materials is compared with that of aluminium. Radiopacity was measured with a method described in the international standard ISO 4049. Specimens of 2 mm thickness and a diameter of 15 mm were prepared according to the manufacturer's instructions. The specimens were placed on a dental X-ray film together with an aluminium step wedge and irradiated. The obtained optical densities were measured with a densitometer and the radiopacity of the test samples was calculated in relation to a similar specimen made of aluminium.

Figure 13 demonstrates the radiopacity of different composite materials. Natural teeth have a radiopacity of 200% Al (enamel) and 100% Al (dentin). Tetric N-Ceram and Tetric N-Flow exhibit a higher radiopacity (Tetric N-Ceram: 400% Al, Tetric N-Flow: 280%) which permits the clear distinction of the restoration and secondary caries on X-rays.

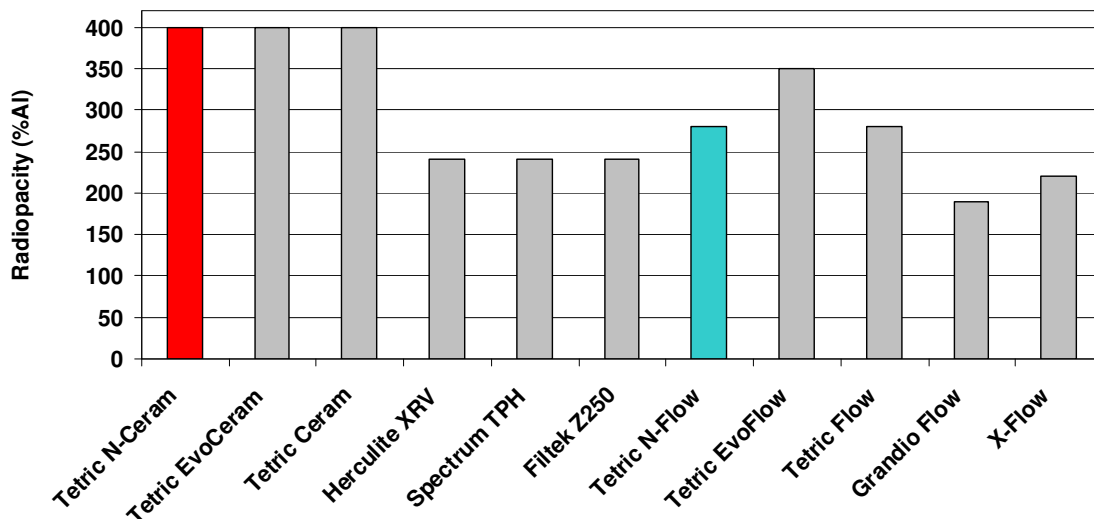


Fig. 13: Radiopacity of selected composite materials. Radiopacity of composite samples were determined according to ISO 4049.

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

3.4 Shear bond strength to enamel and dentin

To test shear bond strength, bovine teeth are embedded in epoxy resin. Enamel or dentin is exposed by grinding and polishing with abrasive paper. Subsequently, the adhesive is applied according to the instructions for use and a composite cylinder with a diameter of 3 mm is incrementally built up and light-cured. After immersion in water for 24 hours at 37 °C, the shear bond strength is measured using a universal testing machine.

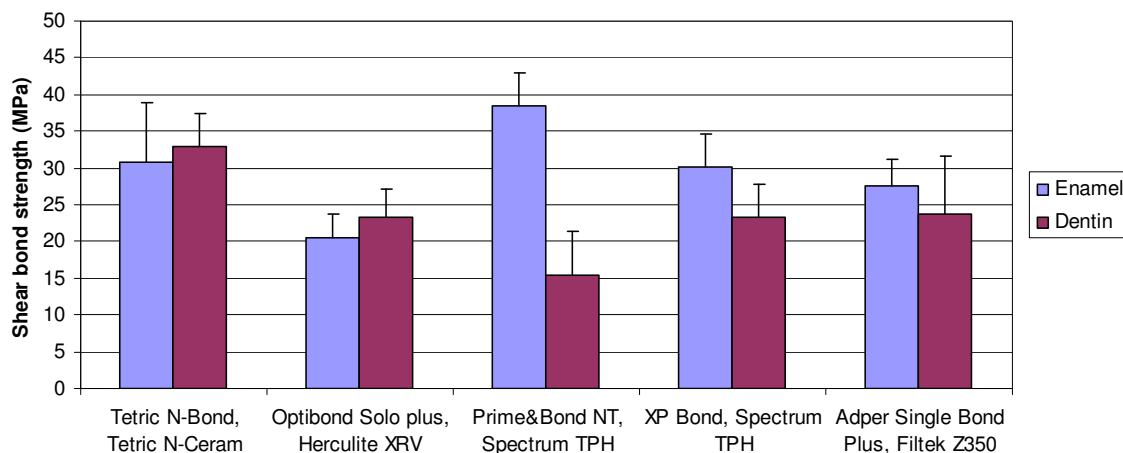


Fig. 14: Shear bond strength of selected composite / adhesive combinations.

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Due to the etching of enamel with phosphoric acid, total-etch adhesives typically achieve higher bond strength on enamel than on dentin. The data obtained show that the total-etch adhesive Tetric N-Bond achieves equally high shear bond strength on enamel and dentin, while the other products tested exhibit lower bond strength on dentin.

3.5 Polymerization shrinkage

During polymerization, all composite materials tend to shrink, as the monomers are cross-linked and need less space / volume in the polymerized material than in the original solution. However, shrinkage results in stress on the adhesive bond and may negatively affect margin quality. Thus, polymerization shrinkage should be as low as possible.

Polymerization shrinkage for different composite materials was determined with a mercury dilatometer after 1 hour. Tetric N-Ceram exhibited slightly higher polymerization shrinkage than the lowest values observed, but the shrinkage was clearly improved compared to Tetric Ceram (see Figure 15).

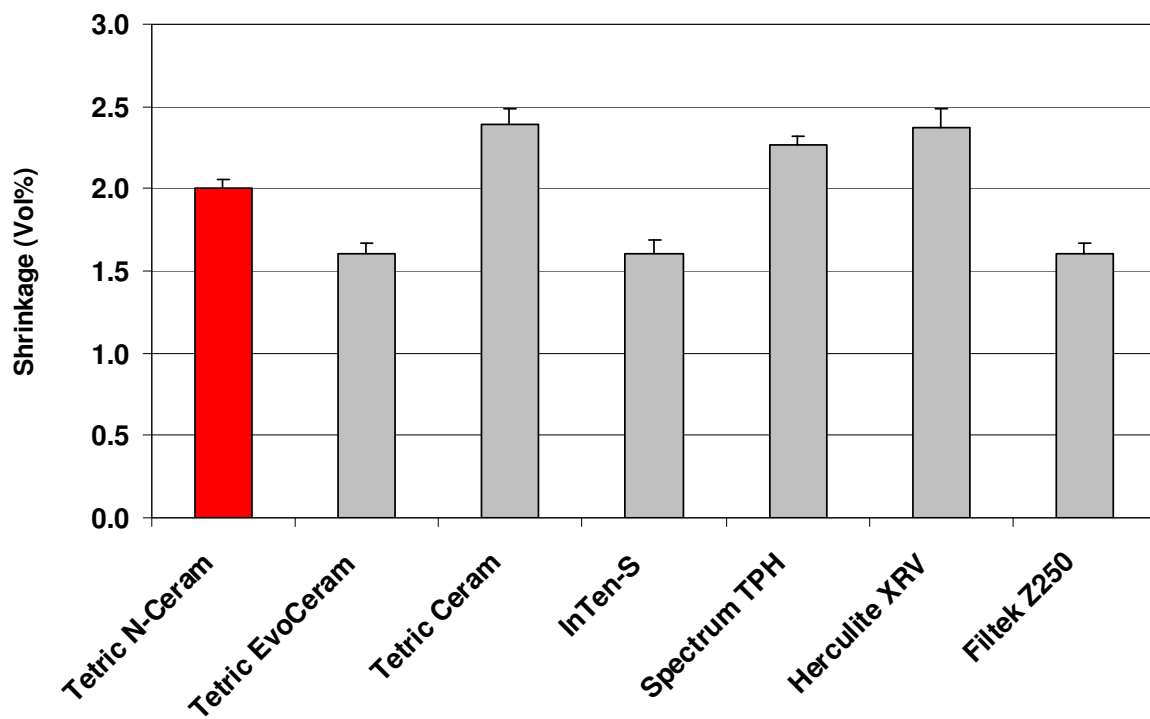


Fig. 15: Polymerization shrinkage of selected composite materials.

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4. Clinical Experience

Tetric N-Ceram, Tetric N-Flow, Tetric N-Bond and Tetric N-Bond Self-Etch were developed employing the know-how gained with previous products of Ivoclar Vivadent. The clinical success of these predecessor products, e.g. Tetric Ceram [19, 20, 22 -24, 29, 30], Tetric [21], Tetric Flow [19, 20; 25-28] AdheSE One [31; 32] and Excite [22; 24; 29; 30], is well documented. Furthermore, in the Tetric N-Collection of products, only raw materials are employed which have already been successfully used in Ivoclar Vivadent products. Therefore, based on the current state of knowledge, the use of Tetric N-Ceram, Tetric N-Flow and Tetric N-Bond and Tetric N-Bond Self-Etch as dental restorative materials is safe and effective for the indicated purpose.

In 2008, a clinical trial using Tetric N-Ceram and Tetric N-Bond has been conducted at the university of Chile by Prof. Dr. Abelardo Báez R. A total of 42 restorations (31 Class I, 11 Class II) were placed in 13 patients. In all cavities, a glass ionomer base was applied as a lining. In one case, calcium hydroxide was required for the protection of the dentin/pulp complex.

Table 2 summarizes the main outcome of this study. No postoperative sensitivity was observed in any of the patients. After 3 months, no restoration losses have been registered; after 6 months, only 2 (4.76%) of the restorations were lost. The 12 months recall has not yet been fully accomplished (21 patients examined).

Table 2: Follow-up examinations and retention of restorations

	3 Months	6 Months	12 Months*
Examined	42 (100%)	40 (95.24%)	21 (50%)
Lost	0	2 (4.76%)	-

* Not all restorations have been examined yet

A detailed summary of the clinical parameters (margin, fracture, marginal gap, secondary caries, discoloration, adequate proximal contact, smooth surface) of the restorations is given in Table 3 providing evidence of the overall excellent clinical performance of Tetric-N Collection products.

Table 3: Evaluation of the restorations

	Perfect margin	Fracture	Marginal gap	Secondary caries	Discoloration	Adequate proximal contact	Smooth surface
3 months	42 (100%)	0	0	0	0	42 (100%)	42 (100%)
6 months	42 (100%)	0	0	0	0	42 (100%)	42 (100%)
12 months	21*	0	0	0	1	9**	21**

* Even though slight discoloration along the margin of one restoration was observed, the margin was considered to be flawless.

** Not all restorations have been examined yet.

5. Biocompatibility Information

5.1 Toxicity and mutagenicity

In Tetric N-Ceram, Tetric N-Flow, Tetric N-Bond and Tetric N-Bond Self-Etch, raw materials identical to those used in previous / other products of Ivoclar Vivadent are employed. These materials have been thoroughly tested for toxicity and mutagenicity. Therefore, they are safe for use in humans with regard to toxicity and mutagenicity.

5.2 Irritation and sensitization

Like all resin-based dental materials, Tetric N-Ceram, Tetric N-Flow, Tetric N-Bond and Tetric N-Bond Self-Etch contain methacrylate and acrylate derivatives. Such materials may have an irritating effect and may cause sensitization. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and by avoiding contact of unpolymerized material with the skin. Commonly employed gloves, e.g., latex or vinyl gloves, do not provide effective protection against the sensitization to such compounds. Allergic reactions are extremely rare in patients, but are increasingly observed in dental personnel who handle uncured composite material on a daily basis [33; 34].

5.3 Conclusions

Tetric N-Ceram, Tetric N-Flow, Tetric N-Bond and Tetric N-Bond Self-Etch do not present a risk in cured or uncured state if used properly. Nevertheless, the well-known sensitizing effect of methacrylates must be taken into account. Patients with a hypersensitivity to these materials are not to be treated. In exceptional cases, dental staff may be affected by contact allergies.

6. References

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