3M ESPE

Glass Ionomer Luting Cement

Technical Product Profile

Ketac™ Cem

Ketac™ Cem Easymix
Ketac™ Cem radiopaque
Ketac™ Cem Aplicap™/ Maxicap™

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Introduction

The clinical success of permanent restorations is primarily a function of the cementation process. The loss of crown retention has been described as one of the most frequent causes for clinical failure of traditional crown and partial tooth restorations. Though adequate tooth preparation for retention purposes remains the most important single factor for the clinical success of restorations, other criteria such as the barrier function against bacterial colonization and the sealing function at the interface of tooth and restoration and as a „mediator“ of different surfaces must also be met by the luting material.

An ideal luting material meets the following requirements:

- Formation of a stable bond between different materials
- Adequate compressive and flexural strength
- Sufficient fracture resistance that prevents restoration detachment due to fractures at interfaces or cohesive fractures
- Favorable flow properties during the approximation to both the tooth structure and the restoration
- Formation of sufficiently thin films of adequate viscosity, permitting complete attachment of the restoration to the tooth stump
- Stability under the ambient conditions inside the mouth
- Biocompatibility
- Favorable processing and setting times

History

Modern dental cements are based on inventions made in the middle of the 19th century. As early as in 1856, Sorel presented a formulation for a magnesium chloride cement. The ensuing search for improved materials initiated numerous developments, such that by the 1920s three main categories of cements had become established: zinc phosphate cements, zinc oxide-eugenol cements, and silicate cements.

In 1966, D.C. Smith introduced yet another class of cement, in which the liquid of the zinc phosphate cement was replaced by aqueous polyacrylic acid. This so-called carboxylate cement opened up new prospects for self-adhesive dental materials.
On the basis of these developments, Wilson et al. introduced glass ionomer cementing materials in 1969, a material class which remains very successful today. The first glass ionomer cement product, ASPA (**A**lumino-**S**ilicate-**P**oly-**A**crylate), introduced in the 1970s, was formulated by adding polyacrylic acid as the liquid component to finely ground silicate powder.
This breakthrough spawned a series of rapid product developments of glass ionomer cements (also termed „GICs“ hereinafter), leading to modifications and improvements to meet the requirements of the broad range of indications of these products. Not even the development of resin materials put a major dent in the continued popularity of these tried and tested biocompatible dental materials.

Rationale

In spite of the increasing popularity of metal-free restorations requiring adhesive fixation, indirect restorations fixed by conventional cementation, such as inlays, cast full crowns, and porcelain fused to metal crowns (pfm), still account for the majority of this kind of indirect restorations. In fact, there is even a marked trend towards fixing single crowns with no metal parts, such as Lava™, Procera™ and In-Ceram™, by conventional techniques, since the materials used in these techniques have proven to be clearly more stable than those used for classical "jacket crowns". Jacket crowns attached by conventional cementation would have been a failure.
A further factor in the continuing popularity of conventional cementation materials is their easy processing, especially in subgingival areas.

Similarly to zinc phosphate cements, which have been occasionally termed obsolete in recent literature, glass ionomer cements are easily processed, stable cementation materials that provide options for numerous applications and effectively resist the ambient conditions inside the mouth.

3M™ ESPE™ has been marketing glass ionomer cements since 1980 (Ketac™ Cem) and assumed a pioneering position in the development of glass ionomer technology. Continued efforts of product development have allowed 3M ESPE to launch new products with improved material properties and simpler or more reliable handling features (see Figure 1) including Ketac™ Cem Aplicap™ and Maxicap™ capsules and a number of filling and core build-up mate-rials. Introduced in 2001, Ketac™ Cem Easymix is the most recent technological addition to 3M ESPE's range of products in this area. Based on the tried and tested luting material, Ketac™ Cem radiopaque, the processing properties in particular have been optimized in this new product.

Glass Ionomer Development

1969	First patent	
1975	First generation	(ASPA)
1980	Second generation	(Ketac™ Cem, Ketac™ Fil, Fuji II™)
1985	Cermet cements	(Ketac™ Silver)
1990	Resin-modified GICs	(Vitrebond™, Photac™ Bond, Fuji LC™)
1994	RMGI luting cements	(RelyX™ Luting, formerly Vitremer™ Luting)
1995	High viscosity GICs	(Ketac™ Molar, Fuji IX™)
2000	Fast-setting GICs	(Ketac™ Molar Quick, Fuji IX™ Fast)
2001	Easily mixable GICs	(Ketac™ Cem Easymix)

Fig. 1: Development of glass ionomer cements

Overview of Technology

From a chemical viewpoint, cements are substances produced by an acid-base reaction. In practical terms, this means that a powder is mixed with a liquid to generate a mixture which then sets and hardens through a setting reaction.

Cements can be classified on the basis of their main components as shown in Figure 2.

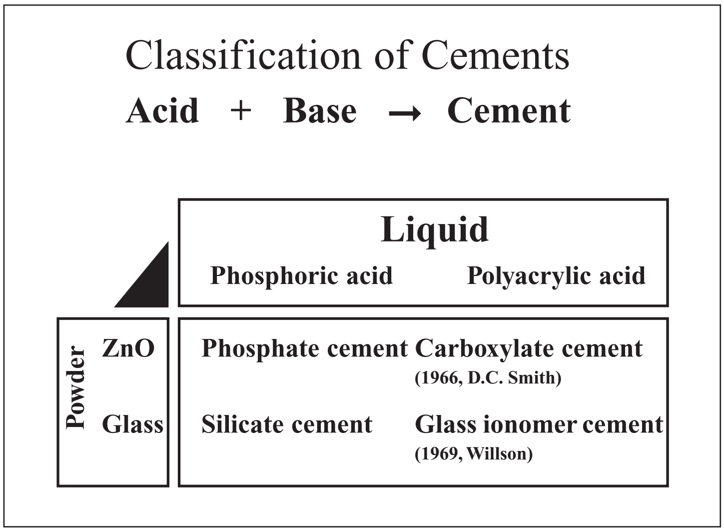


Fig. 2: Classification of cements

The figure shows that glass ionomer cements, such as Ketac™ Cem, are composed of glass powder and polyacrylic acid. Radiopaque glass is used in this application to meet the requirements of the dentist and render the cement radiopaque to X-rays.

Setting Reaction

Since the setting characteristics of the glass ionomer cement are of crucial significance, a short description of these characteristics is provided in the following to provide the basis for a better understanding of the development of this class of materials and their correct application in dentistry. This discussion also highlights the Achilles heel of the earlier glass ionomers.

Once the cement powder is exposed to the aqueous solution of the polycarboxylic acid, a reaction between the alkaline glass powder and the unsaturated acid ensues and a salt gel is formed. Obviously, it is irrelevant in this reaction whether the product is provided in the form of capsules or if powder and solution are manually mixed. The acid-base reaction proceeding in the salt gel leads to the formation of the bonding matrix. Water serves not only as the reaction medium, but also as an essential component of the salt gel as it is required for hydration of the metal-carboxylate complexes formed in the reaction (see Figure 3).

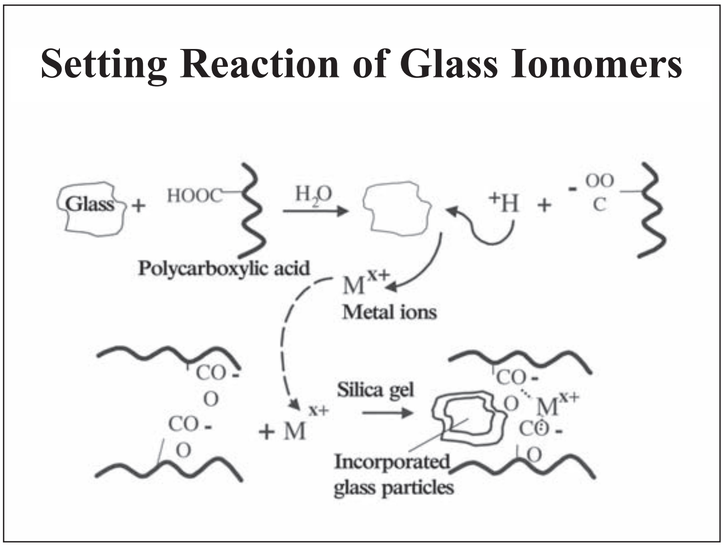


Fig. 3: Schematic depiction of the setting reaction of glass ionomer cements

Details of the Setting Reaction

The setting mechanism can be subdivided into four separate reaction phases.
In the initial phase, the carboxylic acid groups of the polycarboxylic acid dissociate to form negatively charged carboxylate anions, $RCOO^-$, and positively charged protons, H^+. The positively charged protons, H^+, then attack the surface of the glass filling body, causing disintegration of the glass structure and release of the cement-forming metal ions, $Al3^+$ and $Ca2^+$ (see Figure 4).

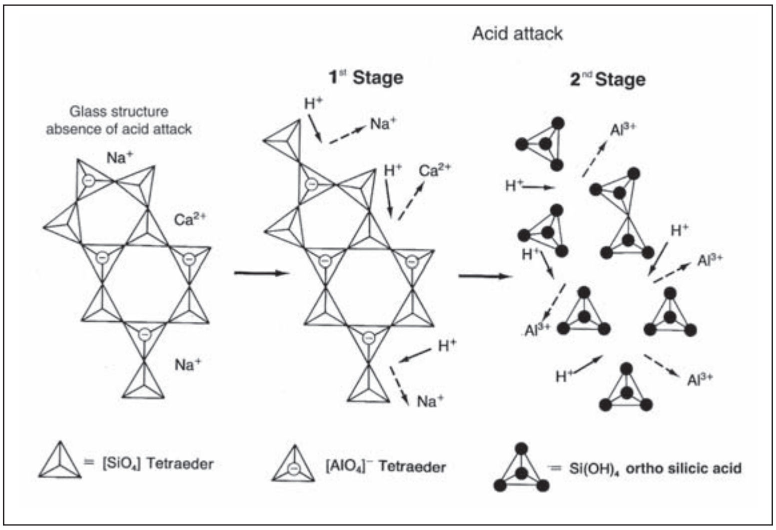


Fig. 4: Structure of an aluminum silicate (Source: A.D. Wilson, J.W. McLean "Glasionomere", Quintessenz Verlag 1988, p. 37)

The influence of fluoride ions at this stage and their ability to form complexes with the released metal ions are discussed in detail later.

The metal ions then enter into the aqueous phase of the cement. Subsequently, the **primary setting phase** commences with the formation of a salt gel (see Figure 5). The released metal ions, M^{x+}, become complex by the carboxylate residues of the polycarboxylic acid component. Calcium ions, Ca^{2+}, are the main active ion species at this stage. The ions are present in aqueous solution, which means that they are quite susceptible to the attack of aqueous solutions (i.e., being washed out).

This is the reason why glass ionomer cements have to be protected from moisture in the first setting phase. However, the opposite effect, i.e. drying out, is no less detrimental, which can be easily explained as the reaction requires an aqueous medium to proceed. The process of hydration is severely impaired or prevented in the absence of water, which limits the supply of ions needed for the setting reaction.

In the course of the reaction, the protons continually attack the silicate glass and cause the release of aluminum ions, Al^{3+}. This initiates the **secondary setting phase**. The incorporation of the trivalent aluminum cations into the preformed matrix leads to the formation of a three-dimensional, water-insoluble calcium-aluminum-carboxylate gel that is no longer susceptible to moisture or dehydration.

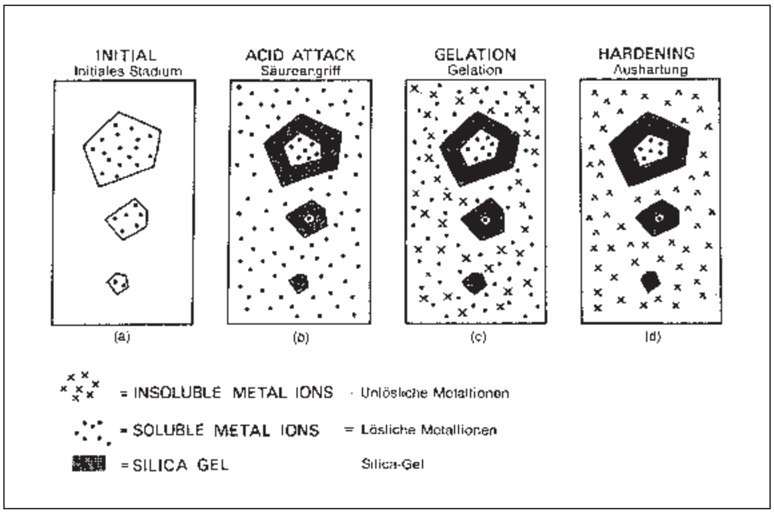


Fig. 5: Formation of the silica gel at the surface of the glass
(Source: A.D. Wilson, J.W. McLean "Glasionomere", Quintessenz Verlag 1988, p. 37)

Factors Influencing the Setting Reaction

Numerous chemical and physical factors can influence the setting properties of glass ionomer cements. Essentially being a simple acid-base reaction, the setting of glass ionomer cements is rendered very complex by the number of different reaction mechanisms involved. This complexity derives not only from the release and precipitation of calcium and aluminum ions, but also from the fluoride- and tartrate ion-mediated process of gel formation. While some factors, such as temperature, powder particle size and powder/liquid ratio simply accelerate or delay the reactions, certain chemical factors have more crucial effects in that they actually modify the reaction processes themselves. The most important factors of this type are fluoride and tartaric acid.

Functions of Fluoride Ions

In the course of their developmental work on glass ionomer materials, Wilson and Kent observed that fluoride-free glasses yield unsuitable pastes that are difficult to process. Crisp and Wilson, and subsequently Barry et al., showed unequivocally that the processing properties are correlated to the amount of fluoride released by the glass. This effect of fluoride ions has been attributed to the ability of fluoride to form metal complexes, which in turn delays the binding of cations (Ca2+, Al3+) to negatively charged sites of the polyelectrolyte chain (see Figures 3-5) and thereby retards gel formation.
This mechanism provides the clinical dentist with sufficient processing time.

Effects of Tartaric Acid

(+)-tartaric acid exerts a unique effect on the glass ionomer reaction. Added in small amounts, tartaric acid simplifies the handling of the cement paste and **increases the stability** of the material. This influence can be explained by tartaric acid's propensity to form stable complexes with aluminum ions, effectively increasing the amount of aluminum released from the glass. Moreover, tartaric acid accelerates the final setting reaction, allowing the setting reaction to show **snap-set properties**.

Indications

The Ketac™ Cem family of products has been in clinical use for some 20 years.
Currently, this line comprises the following products:

- Ketac™ Cem Easymix
- Ketac™ Cem radiopaque
- Ketac™ Cem Aplicap™
- Ketac™ Cem Maxicap™

Ketac Cem is a permanent luting cement based on glass ionomer technology for use in the following applications:

- Cementation of inlays, onlays, crowns, and bridges made from metal or metal-ceramics or covered with composite veneer material
- Cementation of inlays, onlays, crowns, and bridges made from composite or ceramics provided these are suitable for conventional cementing
- Cementation of posts and screws provided these are suitable for conventional cementing
- Luting cement for use on orthodontic bands
- Relinings

(For details of the indications, please refer to the Instructions for Use of the respective product).

Composition

Ketac Cem glass ionomer luting cement comprises powder / liquid components.
Ketac Cem is commercially available both for manual mixing (Ketac Cem radiopaque and Ketac Cem Easymix) and in capsules (Ketac Cem Aplicap and Ketac Cem Maxicap).

The ingredients of Ketac Cem are listed in Table 1.

Material	Powder	Liquid
Ketac™ Cem radiopaque / Easymix	Glass powder Polycarboxylic acid Pigments	Water Tartaric acid Conservation agents
Ketac™ Cem Aplicap™ / Maxicap™	Glass powder Pigments	Polycarboxylic acid Tartaric acid Water Conservation agents

Table 1: Ketac Cem composition

Properties

The selection of a suitable luting cement for a particular application is based on numerous clinical parameters and material requirements. These latter factors principally relate either to handling aspects or to technical material properties.

As mentioned above, Ketac™ Cem has been successfully marketed since 1980. In addition to the experience derived from millions of uses in clinical practice, numerous studies of the material properties as well as controlled clinical studies are available. The following sections provide a detailed discussion of selected results. In addition, numerous publications related to Ketac Cem and some general references on glass ionomers have been assembled in the Literature section of this product profile. The references are supplied with short abstracts to allow the interested reader easy access to primary literature that is of a particular interest to him or her.

Biocompatibility

R.C.S. Chen et al., China Medical College, Taichung, Taiwan
M. Augthun, Klinik für Zahnärztliche Prothetik, Aachen, Germany
W.H.M. Raab et al., Poliklinik für Zahnerhaltung und Parodontologie, Erlangen, Germany
C.H. Pameijer et al., University of Connecticut, USA

The biocompatibility of glass ionomer cements has been the subject of many studies and is extensively documented in the literature.

R.C.S. Chen et al. investigated the **cytotoxicity** of several materials including Ketac Cem. The Ketac Cem results corresponded to the negative control, i.e. the substance showed no cytotoxicity.

A Research Report of Zahnärztliche Prothetik, Aachen, Germany, also investigated the effect of Ketac Cem on cell growth. Conducted in accordance with EN 30993-5, this investigation applied cell culture methods and led to Ketac Cem being classified as a biocompatible material. The cell culture tests showed little or no effect of the substance on cell growth. The tested sample was well tolerated by (i.e. acceptable to) the cells. Taking the in vivo conditions into consideration (flow of saliva), the low inhibitory effect after a short setting time was classified as negligible. The number of samples investigated and the testing methods went beyond the requirements of the standards and thus provided a valid result.

The study conducted by P. Grund and W.H.-M. Raab (Clinic for Conservative and Periodontic Dentistry, Erlangen, Germany) investigated the potential **toxic effect** of the acid component of Ketac Cem on the **pulp** using Laser-Doppler flow measurements to detect changes dental pulp microcirculation. The substances investigated included 33% phosphoric acid, Ketac Cem liquid, and a 35% solution of the acrylic acid-maleic acid copolymer derived from Ketac Cem powder. The results allow to conclude that the free acid components of Ketac Cem are less toxic to the pulp than Tenet (H_3PO_4).

But ultimately, any dental material must prove its value in clinical applications. For this reason, the clinical results have been compiled separately.

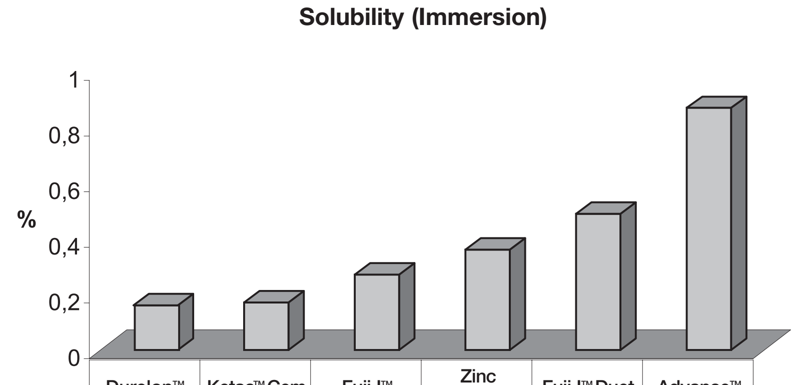
Solubility and Marginal Sealing

K.-P. Stefan, 3M ESPE, Seefeld, Germany
B.K. Norling et al., Dental School San Antonio, USA
S.R. Curtis, Naval Dental School, Maryland, USA
S.N. White, J.A. Sorensen et al., University of Southern California, LA, USA
M. Ferrari, University of Sienna, Italy

Aside from adhesion, the stability of the restoration depends mainly on its erosion and abrasion resistance. Two sub-aspects are of importance in the process of erosion: firstly, the diffusion of soluble components out of the cement, and secondly, the actual erosion due to chemical reactions or mechanical stress. The marginal seal and quality thereof are other important factors in this area.

Usually, the solubility of glass ionomer cements is measured quite some time after setting. The international standard, ISO 7489, proposes determination of the solubility one hour after setting, while the currently applicable standard for cements has the measurements performed after 24 hours. Since neither of these procedures reflects the early exposure to saliva experienced under in vivo conditions, the study of K.-P. Stefan set out to determine the solubilities after 10 min and 60 min. In these studies, the solubility of Ketac™ Cem was shown to be significantly lower than that of a resin-modified glass ionomer cement (ISO 7489).

The study of B.K. Norling et al. compared the two basic study designs for the determination of the **water solubility** and **acid erosion**. Whether or not a given study protocol truly allows a valid comparison of different classes of materials must be evaluated with great care. The literature contains several studies reporting favorable immersion values for Ketac Cem. One of the underlying reasons may be the formulation of this product. Cements with polyacrylic acid in the form of a powder show a trend to have lower solubilities (see Figure 6).



	Durelon™	Ketac™ Cem	Fuji I™	Zinc Phosphate	Fuji I™ Duet	Advance™
Solubility	0,16	0,17	0,27	0,36	0,49	0,87

Fig. 6: Solubility in water, B.K. Norling et al. (see Chapter 11 and Literature, p. 34)

Another important factor in the evaluation of water-based systems is their response to the exposure to moisture during the setting reaction. S.R. Curtis et al. investigated the susceptibility of cements to moisture both before and after removing any excess material and found zinc phosphate cements to respond more sensitively than glass ionomers. Ketac™ Cem does not require application of a protective glaze.

The investigation of Ketac Cem's properties at the margin also yielded some encouraging results. The group of J.A. Sorenson investigated the marginal seal after cementation of cast crowns with polycarboxylate, zinc phosphate, glass ionomer, and composite cements, and found Ketac Cem to be second best only to the composite materials.

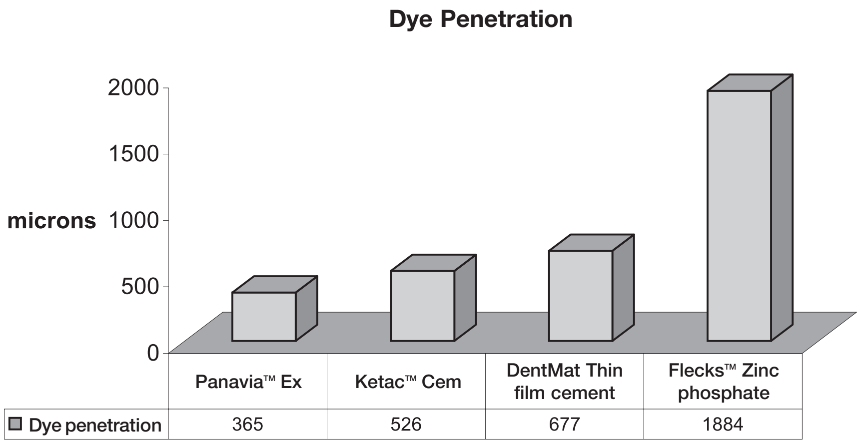


Fig. 7: Dye penetration into cemented cast crowns, Dentin; J.A. Sorensen et al. *(see Literature, p. 31)*

A similar study protocol was used in a study recently published by M. Ferrari, in which the new, manually mixed variant, Ketac™ Cem Easymix, was one of the materials examined. The marginal sealing properties were tested by cementation of cast crowns followed by dye penetration tests. The results showed that there was significantly less leakage with Ketac™ Cem radiopaque and Ketac™ Cem Easymix as compared to the reference groups, Fuji I™ (glass ionomer) and Harvard™ (zinc phosphate).

Figures 8 and 9 show the rating scale and the sample analysis for the "worst case scenario", i.e. dye penetration down to the occlusal cervical wall. None of the samples from the Ketac Cem groups received the worst rating.

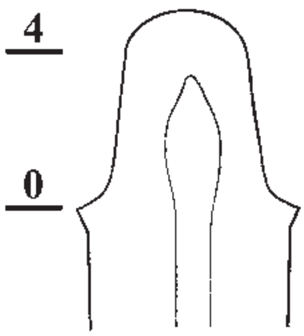


Fig. 8: Dye penetration rating scale; 0 = no dye penetration; 4 = penetration extending to the occlusal cervical wall (see Literature)

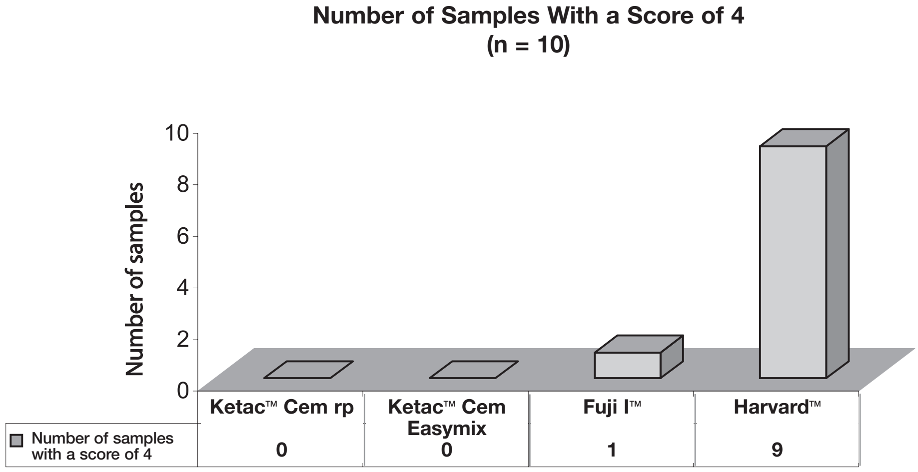


Fig. 9: No. of samples (total n = 10) with dye penetration score 4. M. Ferrari et al. (see Literature, p. 36)

Dimensional Stability and Adhesion

Th.A. Zumstein et al., University of Zurich, Switzerland
C.-P. Ernst, B. Willershausen et al., Universität Mainz, Germany
R. Frankenberger et al., Universität Erlangen, Germany
D.B. Mendoza, University of California, San Francisco, USA
J.M. Casanellas, J.L. Navarro et al., University of Barcelona, Spain
G. Morando, Naval Dental School, Bethesda, USA

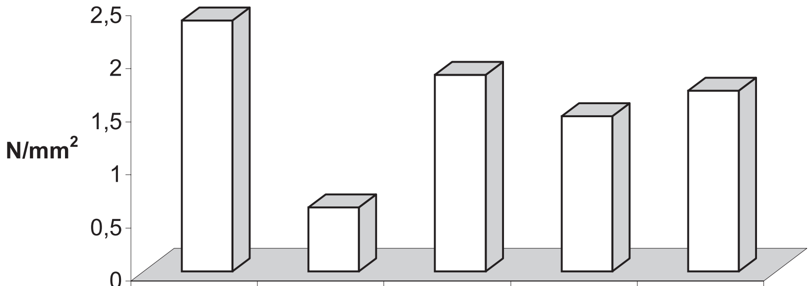
The majority of luting materials expand or shrink more strongly than the tooth structure or are subject to dimensional changes during the setting process or when exposed to moisture and saliva. A characteristic feature of glass ionomer cements is the high dimensional stability and the resulting direct beneficial effect on the marginal gap properties and pressure on the pulp.
In addition, glass ionomer cements show direct chemical bonding to the tooth structure such that there is no need to prepare the cavity for bonding by acid etching or application of a dentin adhesive. The combination of low contraction during the setting process and an expansion coefficient similar to that of teeth explains the favorable marginal gap properties of glass ionomers.

The bonding of glass ionomers to the tooth structure and to metal alloys has been the subject of a large number of in-vitro investigations. The effects of various steps of conditioning also have been well described: Th. Zumstein and J.R. Strub demonstrated that glass ionomers, in general, show stronger bonding to dentin than zinc phosphate materials.[1]

Another interesting result was that Ketac™ Cem attained the highest bonding strength on gold after simple sand-blasting of the substrate, whereas tin-plating and subsequent oxidation reduced the bonding strength.
The literature contains a variety of different methods for determining the bonding strength of luting materials. One suitable method for determination of the retentive and adhesive forces of luting materials involves stripping gold crowns from standardized tooth stumps. A bond strength study conducted at the University of Mainz (Germany) in accordance with this protocol found Ketac Cem to be superior even to the compomer material, F21 (see Figure 10).

[1] In this study, pretreatment of the dentin had a detrimental influence on the bonding strength of Ketac Cem. This observation was accounted for in the clinical recommendation in that Ketac Cem is to be applied to the dentin without pretreatment (and with no conditioner).

Retention Forces

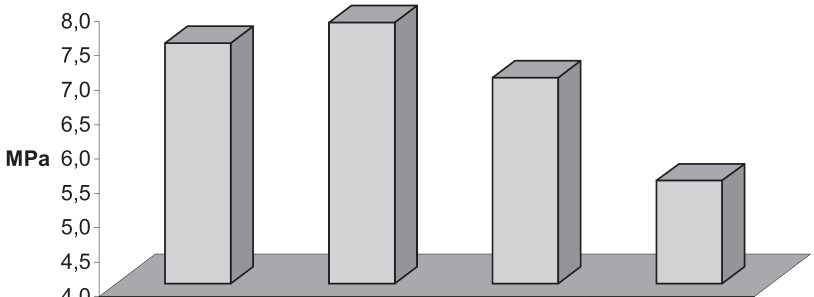


	Ketac™ Cem Easymix	F21	Dyract™ Cem	Dyract™ Cem + P&B 2.0 (non cured)	Dyract™ Cem + P&B 2.0 (cured)
Retention forces	2,36	0,6	1,85	1,46	1,7

Fig. 10: Gold crown tensile test, C.-P. Ernst (see Literature, p. 33)

The push-out test of gold inlays, as established by R. Frankenberger of the University of Erlangen, is another elegant and clinically relevant method. In this technique, non-carious human molars are sectioned into discs and furnished with conical cavities (4°). Subsequently, gold inlays are cemented into these inlay cavities, any excess material is removed, and then the force required to push out the inlay with a stamp is measured (see Figure 11).

Retention Forces

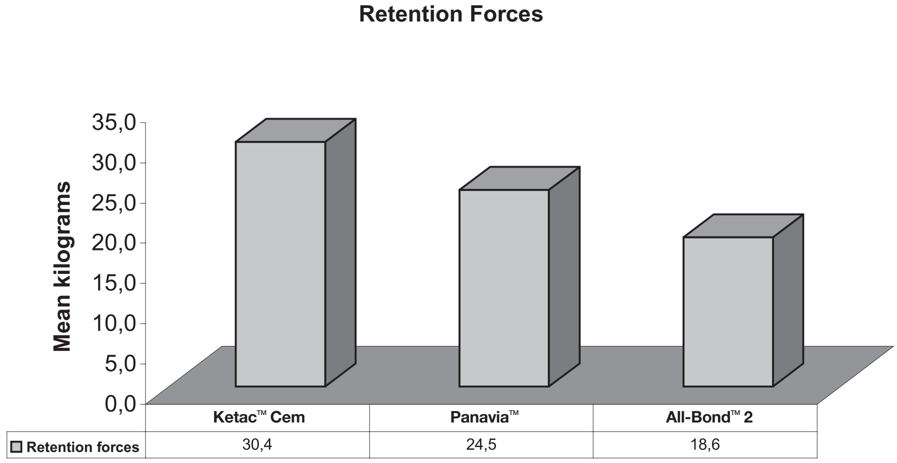


	Ketac™ Cem Easymix	Ketac™ Cem rp	Fuji I™	Harvard™
Retention forces	7,5	7,8	7,0	5,5

Fig. 11: Gold inlay push-out test, R. Frankenberger (see Literature, p. 36)

The two variants for manual mixing, Ketac™ Cem radiopaque and Ketac™ Cem Easymix, attained significantly higher retention values in this test as compared to the Harvard™ zinc phosphate cement. A number of other publications investigated the cementation of **posts, screws, and transfixations** (root canal post implants).

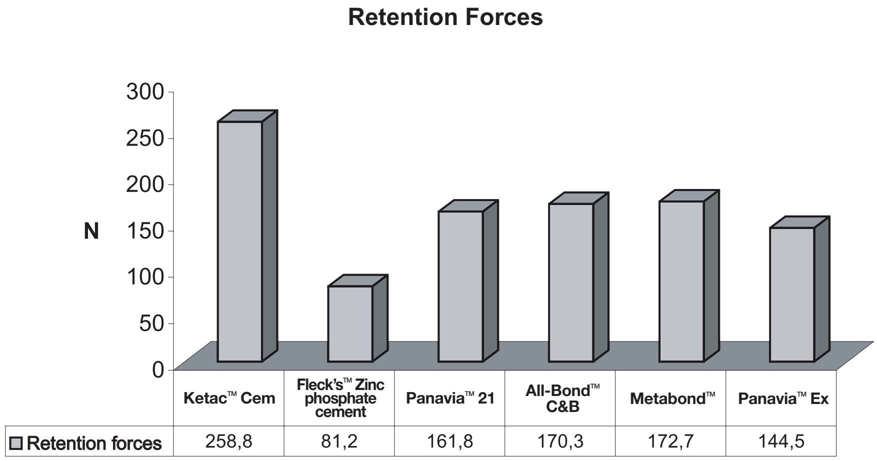
In a study determining the retentive forces of cemented prefabricated metal posts after endodontic treatment of human teeth, Ketac Cem showed even higher strength than the composite materials, Panavia™ and All-Bond™ 2 (see Figure 12). The fact that the glass ionomer cement is easier to process further emphasizes the advantages of Ketac Cem in this indication.



	Ketac™ Cem	Panavia™	All-Bond™ 2
Retention forces	30,4	24,5	18,6

Fig. 12: Retentive forces in the removal of prefabricated posts, D.B. Mendoza et al. (see Literature, p. 32)

A study with an analogous aim was conducted by the Spanish group of J.M. Casanellas and the results confirmed the findings of the earlier scientific study. In the study, Ketac™ Cem was compared to various composite luting materials and zinc phosphate cement with regard to the cementation of prefabricated titanium posts (cylindroconical intraradicular) and showed superior retention forces as compared to all other groups included in the investigation (see Figure 13).



	Ketac™ Cem	Fleck's™ Zinc phosphate cement	Panavia™ 21	All-Bond™ C&B	Metabond™	Panavia™ Ex
Retention forces	258,8	81,2	161,8	170,3	172,7	144,5

Fig. 13: Retention forces in the removal of cemented titanium posts, J.M. Casanellas et al. (see Literature, p. 36)

Aside from retention, a low degree of traumatization is an essential factor for the clinical success of post insertions both with respect to the fracture risk and sensitivity of the tooth. Researchers at the Naval Dental School (Bethesda, USA) developed a specialized in-vitro regimen for investigation of the hydrostatic pressure experienced during post cementation. On the assumption that the experimental design adequately reflects the clinical situation, luting cements building up little hydrostatic pressure are to be preferred in the clinical practice. Figure 14 below shows Fleck's™ zinc phosphate cement to generate the highest hydrostatic pressure which corresponds to the least favorable result.

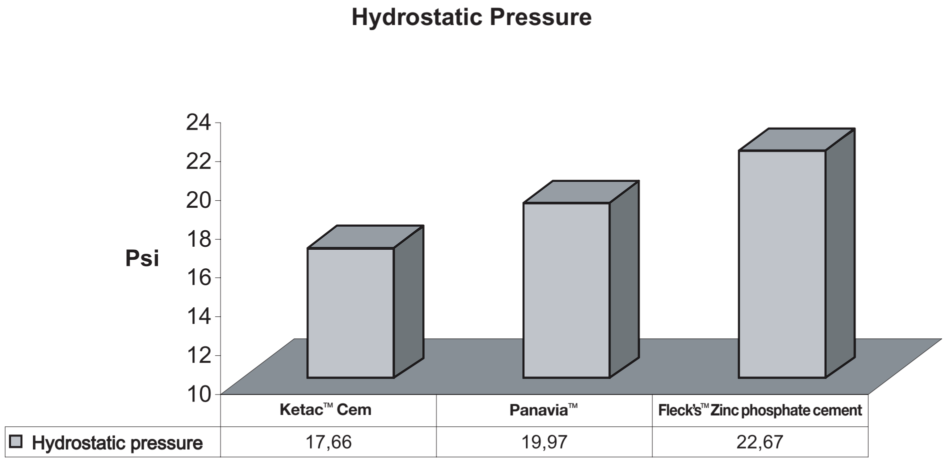


Fig. 14: Hydrostatic pressure, in pounds per square inch, G. Morando et al. (see Literature, p. 32)

Particle Size Distribution and Film Thickness

A. Patyk, M. H. lsmann et al., Universität Göttingen, Germany
J.M. Strutz et al., Loma Linda University and University of Southern California, USA

The generation of thin films is an essential criterion for permanent management with an indirect restoration. Film thickness is determined by a number of different parameters, including particle size, viscosity, flow, and setting properties. The film thickness of aqueous materials for conventional luting particularly varies with processing temperature and humidity (atmospheric moisture content).

The literature data regarding particle size and film thickness show Ketac™ Cem to be an excellent luting cement with favorable particle size distribution which allows the material to form thin films.

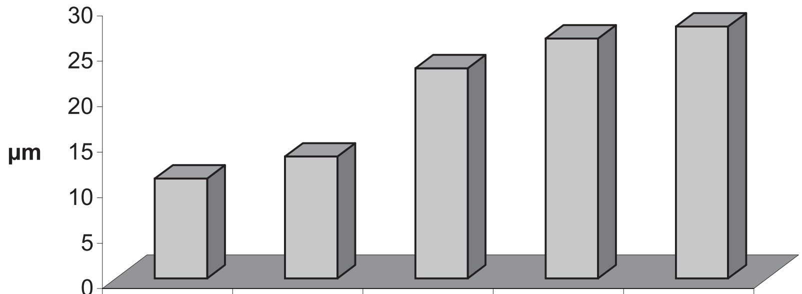
According to a comparative study of six luting materials conducted at the University of Göttingen in Germany, Ketac Cem showed the most favorable results in terms of its particle size and particle size distribution. The sums of the relative frequencies (in %) are shown in the following table:

Particle size, in µm	Ketac™ Cem rp	Fleck's™ Zinc phosphate cement	Fuji™ Ionomer
0.0 - 5.0	81.84	65.88	58.33
0.0 - 10.0	98.36	87.46	91.22
0.0 - 20.0	100	99.58	98.78
0.0 - 30.0		99.76	99.46
0.0 - 40.0		100	99.46
0.0 - 50.0			99.73
0.0 - 60.0			100

Table 2: Particle size distribution, A. Patyk et al. (see Literature, p. 31)

The correlation between the maximal particle size or particle size distribution and the thickness of films of the material was demonstrated in an impressive fashion in studies conducted by researchers at the Loma Linda University and the University of Southern California, Los Angeles. The studies investigated the thickness of films formed by various luting materials in combination with different metal alloys and consistently found Ketac™ Cem to produce the thinnest films. Figure 15 shows the most beneficial combination with a precious nobel metal-ceramic alloy.

Film Thickness



	Ketac™ Cem rp	Durelon™	DenMat Hybrid	Fleck's™ Zinc phosphate cement	Panavia™
Film thickness	11	13,4	23,1	26,4	27,7

Fig. 15: Film thickness of combinations with a precious nobel metal-ceramic alloy, J.M. Strutz et al. (see Literature, p. 32)

Release of Fluoride Ions and Cariostatic Effect

The release of fluoride ions by glass ionomer cements is a known and well-investigated effect. In the proximity of glass ionomer cements, secondary carious lesions develop less frequently than with other dental materials. Due to this effect, this class of material is used in dentures with active caries and in the treatment of secondary caries and in **orthodontic applications**, in which the undesirable demineralization of banded teeth plays a great role.
However, the literature fails to explain the exact mechanism of remineralization and the threshold value of the cariostatic effect of fluoride ions. It is a known scientific fact, though, that the demineralization of the tooth structure occurs at pH<5.5, while remineralization prevails at pH>5.5 (see Figures 16 and 17).

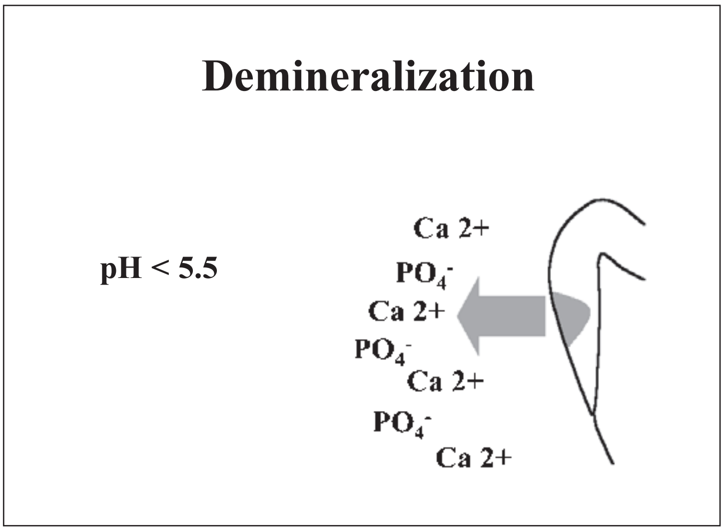


Fig. 16: Schematic depiction of the demineralization process at pH<5.5

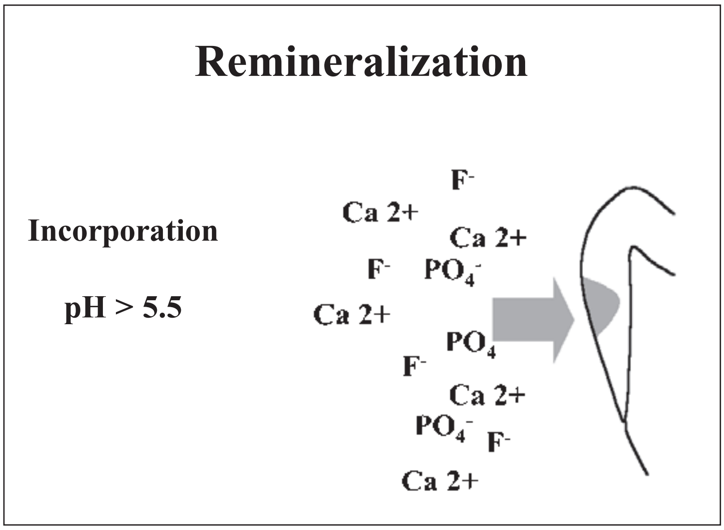


Fig. 17: Schematic depiction of the remineralization process at pH>5.5

Investigations of the pH-dependent fluoride ion release from glass ionomer cements (see Figure 18) showed that fluoride ion release from the material is highest in acidic medium, i.e. when the tooth structure is most severely affected by demineralization. For clinical practice, this may mean that the cement or GIC filling material promotes remineralization best under conditions at which the tooth structure is at risk. This is the underlying rationale for glass ionomer cements being called “smart material”, “intelligent dental material” or “living system”.

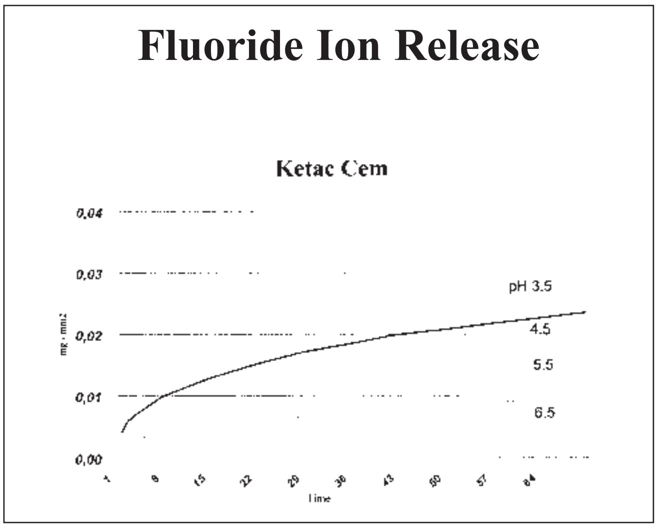


Fig. 18: pH-dependent fluoride ion release by Ketac™ Cem (in-house measurements of 3M ESPE)

Special Features of Ketac™ Cem Easymix

Introduced in September 2001, Ketac Cem Easymix is the most recent addition to the 3M™ ESPE™ Ketac™ Cem product family. The features of Ketac Cem Easymix shall be described in some detail in the following.

The rationale of this product development was to offer our customers who prefer the Ketac Cem variant for manual mixing a product with improved handling features and high reproducibility of dosing, since some users considered the comparatively tedious, yet sensitive mixing of powder and liquid a feature that could be improved upon. A certain degree of familiarity with the mixing technique certainly was of advantage in the past. For this reason, soon after first introducing Ketac Cem in the early 1980s, 3M ESPE followed up by introducing this product in capsules (Aplicap™ and Maxicap™) which make dosing and mixing a simple procedure that reliably yields consistent qualities of material. However, a number of our customers still prefer the variant for manual mixing, e.g. to be able to freely dose the material.

It is for this group of dentists that 3M ESPE developed the new material which combines the features of Ketac Cem and the following added benefits:

- Improved wetting of the powder by the liquid rendering the mixing process much easier and faster
- Reduced dust generation, e.g. during opening of the bottle and dosing and mixing on a mixing pad
- Powder with improved free flowing properties affords better and more reproducible dosing

Technological Background

The advantages described above could only be attained by 3M ESPE by developing and establishing a novel and innovative powder technology. By application of a specialized processing procedure, the primary filling body of the glass ionomer cement is modified such that it can be processed into specialized granulates. Two micrographs of granulate particles are shown in the Figures below. The granulates consist of an agglomerate of individual filling bodies.

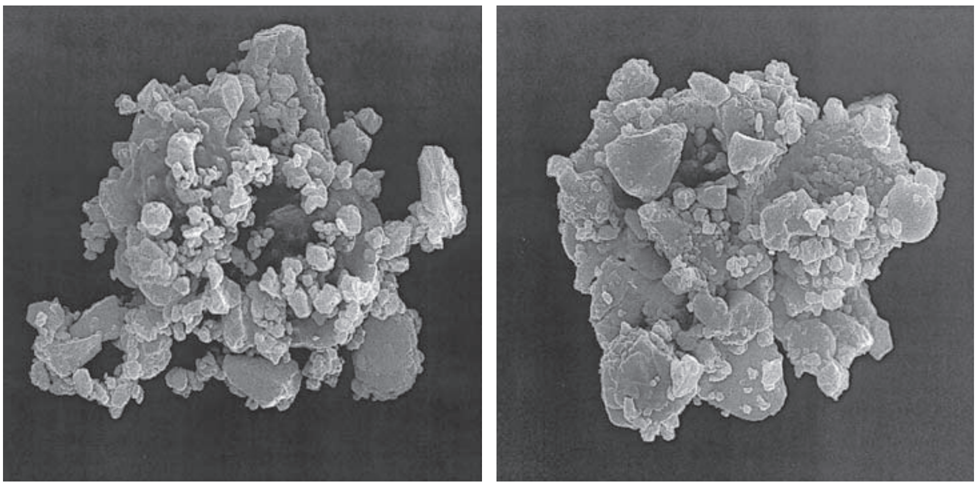


Fig. 19: Ketac™ Cem Easymix granulate; 3M ESPE in-house photographs

The following figure shows the improved liquid adsorption properties of the new Ketac™ Cem Easymix powder as compared to its predecessor, Ketac™ Cem radiopaque, and other glass ionomer materials.

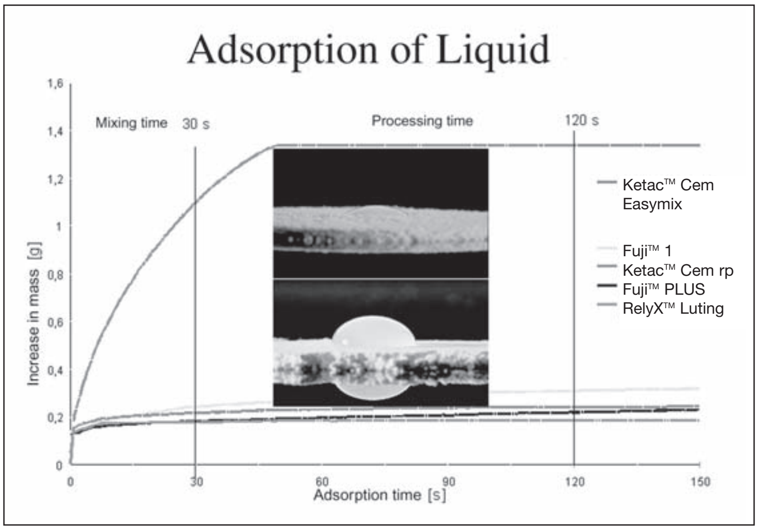


Fig. 20: Time course of liquid adsorption; S. Frank et al. (see Literature, p. 36)

The user is sure to note another advantage of the material. The modified powder is clearly less "dusty". There is no longer any contamination of adjacent areas when the powder bottle is opened or during dosing and mixing. This renders the application of the material in the dental office even more hygienic. Rather than being a subjective observation alone, this effect can be quantified with a dust measuring device like the DustView (Palas), in which the sample powder falls through a vertical gravity tube to reach a dust reservoir. The dust formed upon impact reduces the intensity of laser light transmitted over time. The device allows derivation of initial dust values and also provides some information about the settling of the dust over time. Figure 21 clearly shows Ketac Cem Easymix to possess superior properties as compared to Ketac Cem radiopaque.

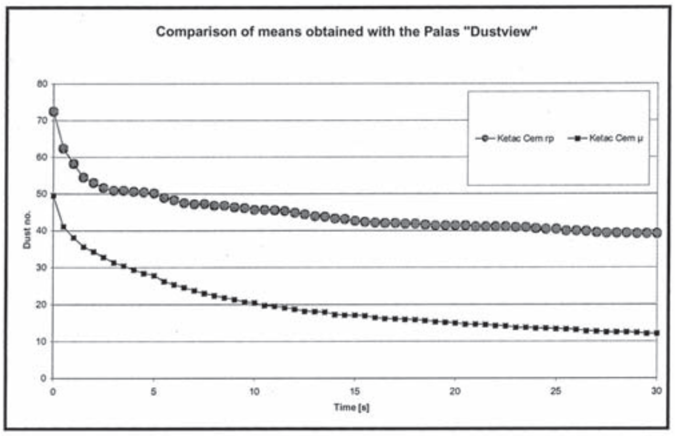
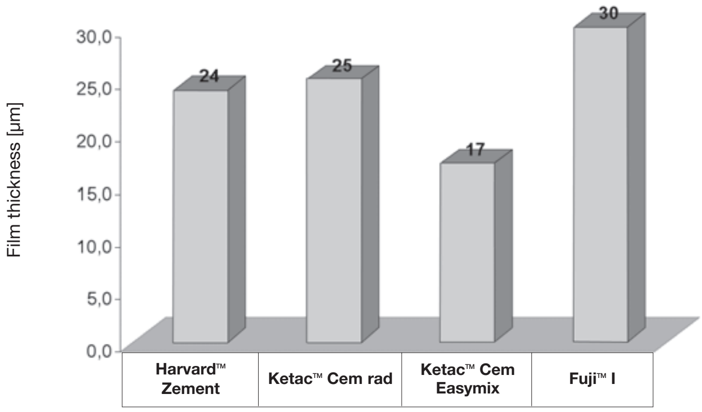


Fig. 21: Analysis of dust measurements with the DustView (Palas); S. Frank et al. (see Literature, p. 36)

Measurements of the film thickness according to ISO 9917 show that the film thickness yielded by Ketac Cem Easymix is at least as good or even lower than that of other conventional cements.
In the ISO 9917 test the mixed cement is sandwiched between two glass plates and a pressure of 150 N is applied after a certain amount of time – here after 20-30 sec.

Film thickness according to ISO 9917*



*The bond was subjected to pressure stress 20-30 seconds after end of mixing time.

Fig. 22: J. Powers, Industrial Report, "Film Thickness of Cements", 2000

Clinical Studies on Ketac™ Cem

Even extensive testing in the laboratory never suffices to completely characterize a product for in vivo application. The ultimate milestone must always be the test of the substance in clinical use or clinical studies. Especially in the first years after glass ionomers were introduced and became established, the materials had the reputation of increasing postoperative sensitivity. This prompted several research groups to conduct controlled clinical studies of this aspect, many of which involved the approach of direct, "split mouth" comparison with zinc phosphate cements.

Study director, center location	Type of restoration	Duration of the study
Prof. Kern, Dr. Kleimeier, Dr. Schaller, Prof. Strub Universität Freiburg	Cementation of: • crowns • partial crowns • bridges	Mean of 17.3 months of wear
Prof. Johnson, Dr. Powell, Dr. DeRouen, University of Washington	Cementation of: • crowns	3 months
Prof. Bebermeyer, Dr. Berg, University of Texas	Short-term study Cementation of: • crowns • partial crowns • onlays	Recall after 1 week
Prof. Sorensen, Dr. Kang, Dr. Torres, Dr. Knode, University of Portland	Cementation of: • 3-unit In-Ceram bridges	3 years

Table 3: Overview of prospective clinical studies on Ketac™ Cem (see Literature)

Comparative Clinical Study of Ketac Cem and a Zinc Phosphate Cement (University of Freiburg, Germany)

Patients with a need for two independent, comparable fixed metal or metal-ceramic restorations were included in this randomized blind study conducted at the University of Freiburg, Germany. One restoration each was cemented with Ketac™ Cem Maxicap™ or Phosphacap™. The study aimed to compare the glass ionomer cement for automatic mixing, Ketac Cem Maxicap, with a zinc phosphate cement under clinical conditions. Particular attention was directed to the issue of postoperative sensitivity.

Study Design

A total of 60 patients between 20 and 70 years of age (mean age: 38.7 years) needing fitting with at least two fixed restorations (crowns, partial crowns or dentures with crown abutment) were included in the study. Overall, 60 restorations were randomly assigned to Ketac Cem Maxicap or Phosphacap each and cemented using a split-mouth design. Follow-up was conducted after one month and in 6-month intervals thereafter. The clinical parameters evaluated included viability of the tooth, secondary caries, retention of the restoration, and development of hypersensitivity.

Results of the Study

The observation period varied between 1 and 33 months (mean: 17.3 months). More than three-quarters of the patients were evaluated between 12 and 17 months after receiving the restorations, whereas only one-third was available for follow-up after 24 to 33 months. None of the follow-ups showed any clinically significant differences between the two cement groups. There was not a single case of loss of viability or need for endodontic treatment and none of the restorations was lost. One case of secondary caries was detected in the zinc phosphate group after 24 months.

Postoperative thermal hypersensitivity was observed in 9 of 60 patients during the first 5 months (7 teeth with glass ionomer, 6 teeth with zinc phosphate cement). All teeth had been fitted with full crowns. Hypersensitivity subsided spontaneously in all cases. In the final follow-up after 33 months, not a single case of thermal hypersensitivity was detected.

Summary

Cementation with glass ionomer versus zinc phosphate cement did not show any difference in the incidence of postoperative sensitivity. This prompted the authors to recommend Ketac™ Cem Maxicap™ as a very good alternative to zinc phosphate cements, especially as the dosage form of capsules provides for easy, reliable and convenient clinical handling of the substance.

Comparative Clinical Study of Ketac™ Cem and a Zinc Phosphate Cement (University of Washington)

Patients in need of management with a full crown who were treated by dental service providers of the US Air Force and Navy were included in a randomized blind study monitored by researchers from the University of Washington. The restoration was fixed with Ketac Cem or Fleck's™ zinc phosphate cement. The aim of the study was to determine if there are differences in the incidence of postoperative sensitivity after the use of Ketac Cem versus zinc phosphate cement. Any differences were to be evaluated in relation to various clinical and technical parameters.

Study Design

Of a total of 214 cemented crowns, 204 were followed up after 2 weeks and 185 crowns after 3 months. The crowns had been fixed with Ketac Cem (n=113) or Fleck's zinc phosphate cement (n=101) by a total of 10 dental service providers of the US Air Force or Navy.

Results of the Study

There were significantly more reports of postoperative sensitivity during the first two weeks in the patients managed with zinc phosphate-fixed restorations as compared to the group with Ketac Cem-cemented crowns. However, in the 3-month follow-up these differences in postoperative sensitivity were no longer detected. Both groups showed less sensitivity in the 3-month follow-up than at baseline.

Summary

The authors concluded that there was no evidence of elevated postoperative sensitivity after cementation with the glass ionomer, Ketac Cem, as compared to zinc phosphate cementing. In addition, the authors found that the sensitivity may be reduced after cementing due to specific properties of the material.

Clinical Short-Term Study Comparing Ketac Cem and a Zinc Phosphate Cement (University of Texas)

Patients needing two independent, comparable crowns or partial crowns were included in a short-term study conducted at the University of Texas (Houston). It was the aim of the study to determine the patient-reported differences in postoperative sensitivity during the initial phase after crowns had been fixed with zinc phosphate or Ketac Cem cement.

Study Design
A total of 51 patients needing at least two comparable crowns or partial crowns were included in this prospective, randomized blind study with split-mouth design. The study was conducted on the population treated in the clinical student teaching course at the University of Texas. Forty-five patients were available for follow-up after 1 week. All patients completed a comprehensive questionnaire that included both open answers and rating scales. The patients were asked to rate the degree of sensitivity of the two restorations using an numeric scale with scores ranging from 1 to 5. The open questions served to provide a more detailed description of the sensitivities (e.g. chronic vs. transient pain, temperature sensitivity, etc).

Results of the Study
No differences in the postoperative sensitivity between the glass ionomer and the zinc phosphate groups were detected. Four patients reported strong pain in a tooth managed with glass ionomer, while three patients of the zinc phosphate group reported strong sensitivity. None of the restorations needed to be replaced or reworked later on.

Summary
This study detected no differences in the incidence or severity of postoperative sensitivity after cementation with glass ionomer versus zinc phosphate cement.

Clinical Study of the Long-Term Success of In-Ceram™ Bridges (University of Portland)

Patients with at least 20 residual teeth and needing at least a 3-unit bridge were included in this prospective long-term study conducted at the University of Portland. The study aimed to evaluate the extension of indications of In-Ceram bridges to premolar and molar restorations. Cementing was performed by a conventional technique using Ketac™ Cem Aplicap™.

Study Design
A total of 61 three-unit bridges were fixed in 47 patients between the ages of 19 and 66 years. One third each of the bridges had the bridge connector at the front teeth, premolars, and molars, respectively. As one requirement, the opposite teeth of bridge units had to be natural teeth or fixed restorations. The manufacturer-recommended indication of In-Ceram bridges was deliberately extended under close control. The restorations were not fixed by adhesive forces, but rather attached conventionally using Ketac Cem glass ionomer cement.

Results of the Study
None of the restorations fixed according to the study protocol gave rise to postoperative sensitivity. None of the stumps had to be subjected to endodontic follow-up treatment prior to the 3-year follow up. Seven of the fixed restorations showed total fracture with none of the fractures manifesting at the frontal teeth, which are included in the indications recommended by the manufacturer. Eleven percent of the fractures occurred in premolar connectors and 24% in restorations of molar teeth.

Summary
From the results of this study, it can be concluded that Ketac Cem is suitable for use in the cementation of In-Ceram restorations.

Instructions For Use

3M™ ESPE™ Ketac™ Cem Easymix

Product Description
Ketac Cem Easymix is a fixing cement for mixing by hand.
For details on 3M™ ESPE™ Alkaliner™ please refer to corresponding information for use. The information for use on the product concerned must be kept available for the length of time it is employed.

Indication

- Cementation of inlays, onlays, crowns, and bridges made from metal or metal-ceramics or covered with composite veneer material
- Cementation of inlays, onlays, crowns, and bridges made from composite or ceramics provided these are suitable for conventional cementing
- Cementation of posts and screws provided these are suitable for conventional cementing
- Luting cement for use on orthodontic bands
- Relinings

Preparation
For maximum possible adhesion, enamel, dentine and metal surfaces must be given a careful cleaning and dried. Avoid excessive drying!

Pulp Protection
The glass ionomer cement must not be applied directly to dentin – e.g. on inlays – situated close to the pulp or to the exposed pulp. Prior to taking the impression, cover areas close to the pulp using a hard-setting calcium hydroxide preparation, e.g. 3M ESPE Alkaliner.

Dosage
Shake bottle to loosen powder. Screw off cap and replace by dispensing dropper. For cementing work, the standard powder-to-liquid mixing ratio is 3.8 : 1 w/w, this corresponding to 1 level spoonful of powder to two drops of liquid. Skim off spoon on plastic segment. Do not compress the powder.
Dose powder and liquid next to each other on a mixing pad or glass slab. Keep bottle upright while dispensing. Crystallized liquid must not be allowed to form on the dispensing dropper. For relinings more powder may be added according to the desired consistency. Carefully seal bottles after use.
If the mix is too thin (due to insufficient dosing of powder) this may produce symptoms of pulpitis.

Mixing
Working of Ketac™ Cem Easymix should proceed at a room temperature of 20-25°C.
Mix using a metal or plastic cement spatula. Add the powder to the liquid in one portion. On principle a sufficient quantity of powder should be added to the liquid to produce viscid consistency. The quantity of cement required for a crown should just about drip from the spatula. Continue to smooth out the paste until a homogeneous mixture is obtained.

Application
During application, water and saliva must be prevented from entering the working area. Apply a thin coat of cement to the inside of the crown and stump. Afterwards proceed with restoration. Avoid overfilling the crown.

Applying hydrostatic pressure buildup in closely adjoining crowns may cause pulp discomfort.

Times
The following time scale applies at a room temperature of 23°C and 50% relative atmospheric humidity:

	min:sec
Mixing	0:30
Application incl. mixing	3:10
Setting from begin of mix	7:00

Higher temperatures shorten the working time, whereas lower temperatures will extend this period (e.g. mixing on a cooled glass slab). A higher amount of powder also brings about a shorter working time. Exceeding the working time causes loss of adhesion to enamel and dentine.

Removal of Excess
Remove excess using a Heidemann spatula and/or probe 6-8 min. after beginning of mix.

Incompatibilities
The product may cause allergic reactions to sensitive persons. If such reactions are experienced, discontinue the use of the product. Pulp complaints may be experienced in rare cases, in particular where working instructions are not properly observed.

Storage and Shelf Life
Keep the powder in a dry place away from damp.
Carefully reseal the powder bottle after each use.
Do not store the product above 25°C.
Do not use after the expiry date.

Questions & Answers

Question:
Ketac™ Cem was inadvertently mixed with water. Do I have to remove a restoration that was fixed despite this mishap?

Answer:
The liquid of Ketac Cem contains water and tartaric acid, and benzoic acid as a conservation agent. The role of tartaric acid is to provide for optimal setting properties and increase the stability by 10%. However, if the restoration has been fixed in the proper place, the setting properties are no longer of concern. A 10% decrease in stability can be tolerated provided there are no other complications.
However, as a matter of principle Ketac Cem should not be prepared by mixing with water.

Question:
Is it possible or advisable to fix full-ceramic crowns with Ketac Cem?

Answer:
This answer depends on the ceramic material used.

Available materials:

- Glass ceramic
- Zirconium oxide or aluminum oxide ceramic

Due to the low inherent stability of **glass ceramics**, the teeth and restorations made from these materials need to be stabilized by formation of an adhesive bond. This bond cannot be generated with Ketac Cem or other glass ionomer cements, but requires the use of a composite luting material and application of the total-etch technique. Moreover, it is advisable to coat the inside of the ceramic crown according to the Rocatec procedure and follow this step up by silanizing with 3M™ ESPE™ Sil™. Fluoric acid etching and subsequent silanization is a suitable alternative. Both procedures provide for optimal bonding between the tooth structure, the luting material, and the indirect restoration.

The inherent strength of the so-called high-strength ceramic materials, such as **aluminum oxide and zirconium oxide**, is sufficient for conventional cementation, i.e. Ketac Cem can be used with this type of material. Please check the manufacturer recommendation to find out whether the ceramic material in question is approved for this type of cementation by the manufacturer.
Initial etching with fluoric acid is not possible in this application. For optimal conditioning of the indirect restoration, use the Rocatec silicatization procedure with ensuing silanization.

Question:
How much material do Ketac Cem capsules contain?

Answer:

Product	Net mass	Dispensable quantity
Ketac™ Cem Aplicap™	260 mg	0.07 ml
Ketac™ Cem Maxicap™	1060 mg	0.36 ml

Question:
How can I distinguish the accessories of Aplicap™ and Maxicap™ products?

Answer:
The accessories for processing of Aplicap products are color-coded in orange.
To be distinguishable, the accessories for processing of Maxicap products are color-coded in blue.

Summary

Cementation is an essential step in the management of patients with indirect restorations. The requirements on both the handling and material properties of the substances used for cementation are high.
Ketac™ Cem has been on the market since the 1980s and has demonstrated its utility in millions of uses in clinical practice. Moreover, Ketac Cem has been the subject of extensive scientific studies and often has been described in the literature as the "Gold Standard" for conventional cementation.

Ketac Cem is both easy and convenient to use. The capsule version of the product provides a **pre-dosed dosage form for automatic mixing** which effectively prevents dosing and mixing errors. However, manual dosing and mixing has also become much more convenient since the introduction of Ketac™ Cem Easymix. Additional beneficial features of the material simplifying the clinical handling include the **consistency of the material, which provides for both stabi-lity and free-flowing properties**, and the **ease with which any excess material can be removed**.

As was outlined above, Ketac Cem has been extensively investigated in scientific studies covering all essential requirements.
The high level of **biocompatibility** accompanied by **good marginal sealing properties, low solubility**, and **high resistance to mechanical stress** are features assuring long-term clinical success. Due to its high **dimensional stability**, Ketac Cem protects the pulp from hydrostatic pressure as the result of which Ketac Cem is a simple and user-friendly cementation material that can also be used with high-strength ceramic materials. Especially in comparison to the zinc phosphate cements, the **inherent adhesive properties** of this glass ionomer cement, which afford bonding to the tooth structure and metal parts, is a great advantage. It goes without saying that the **thin films** of the material allow for ideal fitting of indirect restorations.

The extraordinary clinical utility of Ketac Cem has been demonstrated not only in material science studies, but also in clinical investigations. A selection of these studies has been discussed before.

Literature

Literature on Ketac™ Cem

Th.A. Zumstein, J.R. Strub,
Zementhaftung (Cement bonding), Schweiz. Mschr. Zahnheilk. **1981**, 91 (4), 196-205.

The dependence of the adhesion properties of three cements on the dentin and metal pre-treatment method was investigated. GICs showed higher bonding strength as compared to zinc phosphate cements. The highest bonding strength for Ketac Cem was observed with untreated dentin and sand-blasted gold.

Th. Zumstein, J.R. Strub,
Adhesion of Cement, Quintessence Int **1983**, 14, 1-8.

H.W. Seeholzer, W. Dasch,
Befestigung von Bändern mit einem Glasionomerzement (Adaptation of bands with glass ionomer cement),
Informationen aus Orthodontie und Kieferorthopädie **1986**, 18 (1); 89-96.

The use of bands always carries the risk of marginal gap formation and de-mineralization of the enamel. Due to their good adhesion to metals and direct chemical bonding to dentin and enamel, glass ionomer cements are suitable for use in banding. The restrictions imposed by the relatively short processing time and moisture-sensitivity of the first setting phase of Ketac Cem are well accounted for in the "two-step band adaptation" method.

H.W. Seeholzer, W. Dasch,
Banding with Glass Ionomer Cement, J. Clinical Orthodontics **1988**, 12 (12).

1. *Comparison of the material properties of Ketac Cem and phosphate cement.*
2. *Clinical study on orthodontic bands. Even in the absence of mechanical abrasion of the bands, the use of Ketac Cem was associated with 19.7% fewer losses as compared to the control group using zinc phosphate cement.*

P. Grund, W.H.-M. Raab,
Zur Pulpatoxizität der Säurekomponente von Befestigungszementen (On the pulpal toxicity of acid components of luting cements),
Dtsch. Zahnärztl. Z. **1990**, 45 (9).

Laser-Doppler flow measurements were used to determine changes of the microcirculation of the pulp effected by 33% phosphoric acid, Ketac Cem liquid, and a 35% solution of the acrylic-maleic acid copolymer of Ketac Cem powder. The results of the study allow to conclude that the free acid components of Ketac Cem show lower pulpal toxicity as compared to Tenet (H_3PO_4).

B. Kleimeier, H.G. Schaller, M. Kern, J.R. Strub,
Is the Glass-Ionomer Luting Cement an Alternative to Zincoxyphosphate Cement?,
IADR meeting **1991**, Acapulco.

No clinical difference between zinc phosphate and Ketac Cem was detected in the 1-year-recall. There was no evidence for the commonly held view that GICs generate higher postoperative sensitivity than zinc phosphate cement.

F. Rezk-Lega, B. Øgaard, J. Arends,
An in vivo study on the merits of two glass ionomers for the cementation of orthodontic bands,
Am J Orthod Dentofac Orthop **1991**, 99, 162-167.

It was shown in this in-vivo study on orthodontic bands that GICs may reduce the enamel demineralization. Ketac Cem showed significantly better results than Aqua Cem™.

G.H. Johnson, L.V. Powell, T.A. DeRouen,
Pulpal Sensitivity from Zinc Phosphate and Glass Ionomer Cements Following Crown Cementation,
IADR Meeting, Glasgow, **1992**.

S.N. White, J.A. Sorensen, S.K.Kang, A.A. Caputo,
Microleakage of new crown and fixed partial denture luting agents,
J. Prosth. Dent. **1992**, 67 (2), 156-161.

Determination of the degree of microleakage in cast crowns following cementation with polycarboxylate, zinc phosphate, glass ionomer, and composite cements. Ketac Cem was second best only to the composite cements.

M. Kern, H.-G. Schaller, J.R. Strub,
Microleakage of new crown and fixed partial denture luting agents,
J. Prosth. Dent. **1992**, 67 (2), 156-161.

G.H. Johnson, L.V. Powell, T.A. DeRouen,
Evaluation and Control of Postcementation Pulpal Sensitivity: Zinc Phosphate and Glass Ionomer Luting Cements,
JADA **1993**, 124, 39-46.

After being in situ for two weeks, the zinc phosphate cement group showed significantly more frequent postoperative complaints than the Ketac Cem group.

A. Patyk, M. Hülsmann, S. Rinke,
Untersuchung zur Partikelgröße zahnärztlicher Befestigungszemente (Determination of the particle size of dental luting materials),
Dtsch Zahnärztl Z **1993**, 48, 372-375.

The particle size distribution of 6 different dental luting materials was compared. In this study, the glass polyalkenoate cements showed a more favorable particle size distribution as compared to carboxylate cements. However, the most favorable maximal particle size (20 µm) and particle size distribution was detected in the glass polyalkenoate cement, Ketac Cem.

S.R. Curtis, M.W. Richards, J.C. Meiers,
Early Erosion of Glass-Ionomer Cement at Crown Margins,
Int J. Prostodontics **1993**, 6 (6), 553-557.

Ketac Cem must be protected from moisture for approx. 10 min. Once the excess material is removed, the material needs no further protection, e.g. by application of Ketac™ Glaze. Zinc phosphate cements are more sensitive to moisture than GICs.

R.D. Berbermeyer, J.H. Berg,
Comparison of patient-perceived post cementation sensitivity with glass-ionomer and zinc phosphate cements,
Quintessence Int **1994**, 25 (3), 209-214.

Randomized, split-mouth design study on partial and full gold crowns. Both phosphate cement and Ketac™ Cem were evaluated. One week postoperatively, the patients were interviewed with a questionnaire regarding their experience with postoperative complications. No differences between the study groups were detected.

J.M. Strutz, S.N. White, Z. Yu, C.L. Kane,
Luting cement-metal surface physicochemical interactions on film thickness,
J. Prosth. Dent. **1994**, 72 (2), 128-132.

The results regarding the film thickness determined in this study showed the glass ionomer cement, Ketac Cem, to generate the thinnest films with all types of metal. The observed differences were significant.

D.B. Mendoza, W.S. Eakle,
Retention of posts cemented with various dentinal bonding cements,
J. Prosth. Dent. **1994**, 72 (6), 591-594.

Second only to C&B Metabond™, Ketac Cem attained the highest bonding strength of all cements in the cementation of endodontic posts. The results were superior even to those of the composite materials, Panavia™ and All-Bond™ 2. The fact that the glass ionomer cement is also easier to process further emphasizes the advantages of Ketac Cem in this indication.

G. Morando, R.J. Leupold, J.C. Meiers,
Measurement of hydrostatic pressures during simulated post cementation,
J. Prosth. Dent. **1995**, 74 (6), 586-590.

Strong pressure during the cementation of intracoronal posts may induce root fractures. However, reduced pressure often causes the post to be improperly seated. In a simulated in-vitro study, the use of Ketac Cem generated the lowest pressure during the cementation of gold posts.

D.T. Millett, J.F. McCabe, T.G. Bennett, N.E. Carter, P.H. Gordon,
The Effect of Sandblasting on the Retention of First Molar Orthodontic Bands cemented with Glass Ionomer Cement, Br. J. Orthodontics **1995**, 22, 161-169.

In-vivo (split-mouth) and in-vitro application of Ketac Cem.

T. Morneburg, A. Schulz,
Zum Einfluss der Sealer auf die Retention unterschiedlicher Stiftimplantate im Wurzelkanal (On the influence of sealers on the retention of different post implants in the root canal), Zahnärztl Implantol **1995**, 11, 105-110.

Fixation of post implants in the root canal (transfixation). Ketac™ Cem and Harvard™ cement are recommended as suitable materials for practical use.

M. Kern, B. Kleimeier, H.-G. Schaller, J.R. Strub,
Clinical comparison of postoperative sensitivity for a glass ionomer and a zinc phosphate luting cement, J. Prosth. Dent. **1996**, 75 (2), 159-162.

The recall after 17.3 months revealed no clinical difference between zinc phosphate and Ketac Cem. There was no evidence whatsoever supporting the commonly held view that GICs gene-rate higher postoperative sensitivity. The study investigated single crowns, partial crowns, and crowns being components of fixed restorations.

Y. Gömeç, I. Duman,
Bond Strengths of Different Casting Inlay Alloy-Luting Cement Systems,
IADR / CED meeting, **1996**, Berlin.

Ketac Cem showed higher bonding strength with various metal alloys as compared to polycar-boxylate or zinc phosphate cement.

C.-P. Ernst, N. Wenzl, B. Willershausen,
Adhesive strength of a new compomer cement, IADR/CED meeting, Berlin, **1996**.

Bonding is the essential feature determining the clinical success of cemented gold crowns and depends both on the preparation and the type of cement used. Ketac Cem and Dyract™ Cem yielded significantly better results than F21.

M. Augthun,
Erfassung der zellwachstumsbeeinflussenden Wirkung von Ketac Cem,
Unveröffentlichte Ergebnisse: Forschungsbericht Klinik für Zahnärztliche Prothetik Aachen (Determination of the effects of Ketac Cem on cellular growth; unpublished results: A Research Report), 1996.

Conducted in accordance with EN 30993-5, this investigation applied cell culture methods and led to Ketac Cem being classified as a biocompatible material. The cell culture tests showed little or no effect of the substance on cell growth. The tested sample was well tolerated by (i.e. acceptable to) the cells. Taking the in vivo conditions into consideration (flow of saliva), the low inhibitory effect after a short setting time was classified as negligible. The number of sam-ples investigated and the testing methods went beyond the requirements of the standards and thus provide a valid result.

Permanent Cements,
The Dental Advisor 1997, 14 (2), 1-8.

Clinical Rating of Ketac™ Cem Maxicap™ and Ketac™ Cem radiopaque.

B.K. Norling, J.O. Burgess, J.M. Powers, H.L. Cardenas,
Immersion and Jet Erosion Solubilities of Fluoride Releasing Cements,
J. Dent. Res. **1997**, 76 (IADR Abstracts) 210.

Ketac™ Cem showed low solubility in both tests of this study.

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Partial crown 16, MOD inlay 17, User Report) Dental Magazin **1998**, 3.

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Ketac Cem Maxicap,
The Dental Advisor 1998, 15 (2), 6.

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T.J. Gillgrass, D.T. Millett, S.L. Creanor,
In Vitro Assessment of Microleakage for Two Orthodontic Band Cements,
IADR meeting, Nice, **1998**, Abstract # 1416.

The microleakage properties of orthodontic bands after cementation were investigated.

T.A. Örtendahl, B. Thilander,
Use of glass-ionomers for bracket bonding - an ex in vivo study evaluating a testing device for in vivo purposes,
European Journal of Orthodontics **1998**, 20, 201-208.

GICs for condensation polymerization (including Ketac Cem) are suitable materials for orthodontic applications. It is sufficient to pretreat to the degree recommended by the manufacturer: additional measures afford no improvement in the bonding to the tooth structure.

J.A. Sorensen, S.-K. Kang, T.J. Torres, H. Knode,
In-Ceram Fixed Partial Dentures: Three-Year Clinical Trial Results,
CDA Journal **1998**, 26 (3), 207-214.

3-year recall of 3-unit In-Ceram™ bridges. All restorations had been fixed with Ketac Cem: no postoperative sensitivity was observed and no endodontic follow-up treatment was required. Ketac Cem can be recommended for the cementation of In-Ceram-fixed partial dentures.

R.C.S. Chen, L.R. Chiou, K.H. Chen,
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IADR meeting, Nice, **1998**, Abstract #1441.

Ketac Cem showed no cytotoxity and was identical to the negative control.

C.-P. Ernst, N. Wenzl, E. Stender, B. Willershausen,
Retentive strengths of cast gold crowns using glass ionomer, compomer, resin cement, J. Prosth. Dent. 1998, 79 (4), 472-476.

Dyract™ Cem and Ketac Cem showed better retention than F21.

K.-P. Stefan,
Early solubility of glass ionomer cements,
IADR meeting, Nice, **1998**, Abstract # 454.

It is customary to measure the solubility of GICs at a time long after setting is complete (1 h pursuant to ISO 7489; 24 h pursuant to ISO 9917). However, this fails to adequately reflect the in vivo situation characterized by early exposure to saliva. This study reports the solubility values of GICs after 10 and 60 min.

K. Thedens,
Prothetik-Zyklus '98 - '99; Ein Fallbeispiel aus dem zahnärztlichen Praxisalltag; Teil 3: Die provisorische und definitive Eingliederung (A case report from common dental practice; part 3: temporary and permanent fixation),
Zahnarzt Magazin 1999, 1.

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H. Lammers,
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Quadranten-Sanierung mit System (From impression taking to permanent management: systematic quadrant regeneration), Dental Spiegel **1999**, 4.

Quadrant regeneration (tooth 14 and 15) with In-Ceram™ ceramics and management of tooth 16 and 17 with high gold content, palladium-free partial crowns.

Z.C. Li, S.N. White,
Mechanical properties of dental luting cements,
J. Prosth. Dent. **1999**, 81, 597-609.

Current overview of classes of materials and investigations of materials science. GICs were convincing mainly because of the low tendency to form marginal gaps and good crown retention.

G. Eickemeyer, P. Rammelsberg, P. Pospiech, W. Gernet,
In-vitro study of fracture resistance of metal-free Artglass crowns,
J. Dent. Res. **1999**, 78, 158. (IADR meeting 1999, Vancouver, Abstract # 421)

The fracture resistance of Artglass crowns after thermocycling was significantly better with the adhesive technique or Ketac™ Cem as compared to Zinc phosphate cement.

M. Rosin, M. Wilkens, A. Welk, C. Splieth, G. Meyer,
Effect of cement type on retention of a prefabricated tapered post,
CED Meeting, Montpellier, **1999**.

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J.M. Casanellas, J.L. Navarro, A. Espias, X. Gil,
Retention of a cylindroconical post comparing various cements,
IADR/CED meeting, Madrid, **1999**, Abstract # 421.

Ketac™ Cem yielded the most favorable results in the cementation of metal posts.

M. Martin, C.-P. Ernst, B. Willershausen,
Ketac Cem: Eine Literaturübersicht (A literature overview),
ZWR **2000**, 109 (7/8), 388-391. ZWR **2000**, 109 (9), 475-481.

Short overview of/about cement classes. Literatur overview of in-vitro and in-vivo results on Ketac™ Cem.

S. Frank, J. Glaser, H. Nirschl, G. Rackelmann, K.-P. Stefan,
Dust formation and wettability of glass ionomer powders,
AADR meeting, Chicago, **2001**, Abstract # 1303.

Due to its exellent wettability and reduced tendency to generate dust, Ketac™ Cem Easymix represents a clear improvement in terms of the handling of glass ionomer cements for manual mixing.

B. Windmüller, M. Ferrari,
Influence of Conventional Luting Materials on Leakage of Gold Crowns,
IADR meeting, Chiba, **2001**, Abstract # 1862.

Ketac™ Cem radiopaque and Ketac Cem Easymix showed less dye penetration than the other materials tested, Fuji I™ and Harvard™ Zinc phosphate cement.

R. Frankenberger, H. Oberschachtsiek, A. Teubner, N. Krämer,
Retentive Strengths of Cast Gold Inlays Luted with Different Cements,
IADR / CED meeting, Rom, **2001**, Abstract # 344.

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General Literature

A.D. Wilson, J.W. McLean,
Glasionomerzement (Glass Ionomer Cement), Quintessenz, Berlin, **1988**.
Textbook.

Ed. W. F. Wathen,
The glass ionomer cement, JADA **1990**, 120, 19-68. Theme issue

Including:
D. C. Smith,
Composition and characteristics of glass ionomer cements,
JADA **1990**, 120, 20-22.

GICs are suitable for use in filling, lining, fixation, and prophylactic applications. The properties of the material are dominated by factors like composition, processing, and application. In general, being stable and strong materials that bond to the tooth structure, GICs may show a low degree of toxicity and potentially have an anti-cariogenic effect.

G.J. Christensen,
Glass ionomer as a luting material, JADA **1990**, 120, 59-62.

Cariostatic activity, dimensional stability (expansion and shrinking), material properties, such as strength and E-modulus, bonding to the tooth structure, flow properties, lowest solubility of all cements.

H. Schuh,
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Chemical function of a glass ionomer and resin-modified glass ionomer cement.

S.F. Rosenstiel, M.F. Land, B.J. Crispin,
Dental luting agents: A review of current literature,
J. Prosth. Dent. **1998**, 80 (3), 280-301.

Overview of the current literature on dental luting cements.

A.M. Diaz-Arnold, M.A. Vargas, D.R. Haselton,
Current status of luting agents for fixed prosthodontics,
J. Prosth. Dent. **1999**, 81 (2), 135-141.

Review of 5 classes of luting materials with an emphasis on the advantages and disadvantages and indications.

C.L. Davidson, I.A. Mjör,
Advances in Glass-Ionomer Cements, Quintessence, Chicago, **1999**.
Textbook.

K. Stefan in,
Ullmann's Encyclopedia of Industrial Chemistry, Dental Materials
(Chapter: cements), Electronic Release, Wiley, **2000**.

Overview of the classes of materials including history, chemistry, and benefits.

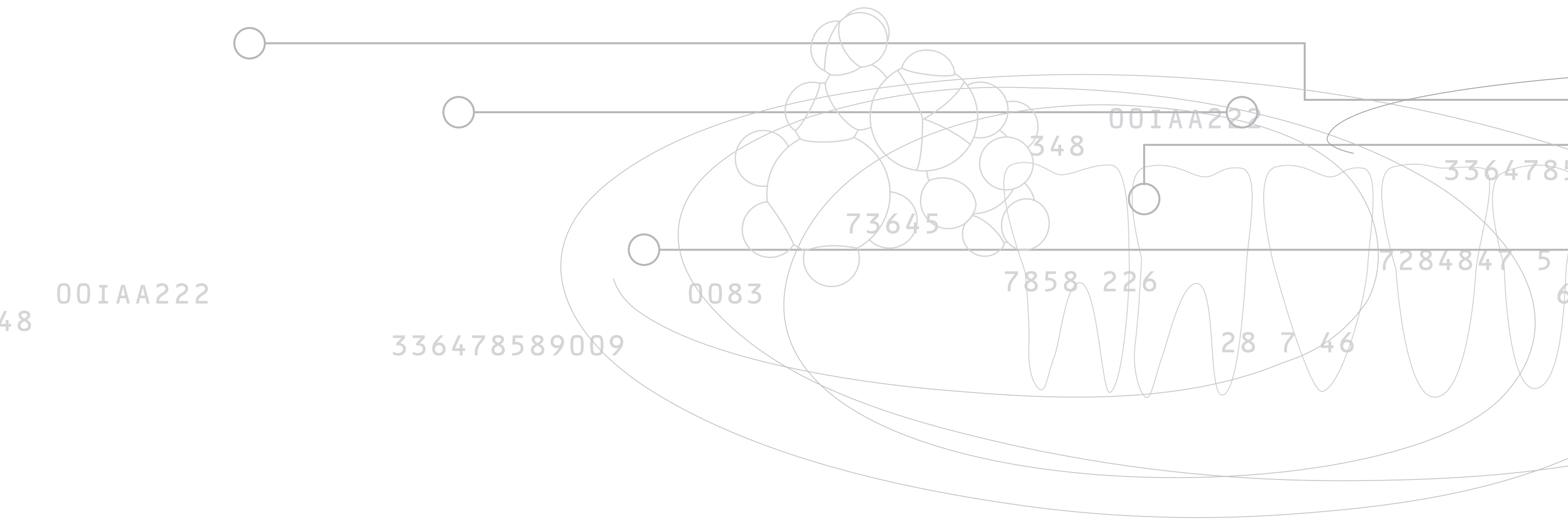
Technical Data

3M ESPE in-house measurements according to ISO standards

Test:	Film thickness	Setting time	Compressive strength	Surface hardness	Flexural strength	Radio-opacity
Test methods. Limit: Measure unit:	ISO 9917 <25 µm µm	ISO 9917 2:00 - 6:00 min:sec	ISO 9917 >70 MPa MPa	DIN 53456 MPa	ISO 4049 MPa	ISO 4049 %
Ketac™ Cem radiopaque 3M ESPE # 0064075	18 ± 1 (1:30)	03:45	140 ± 14	207 ± 15	12 ± 5	152
Ketac™ Cem Easymix 3M ESPE # USA-G301	17 ± 2	03:00	141 ± 14	235 ± 25	15 ± 5	n.d.
Ketac™ Cem Aplicap™ 3M ESPE # 0024	16 ± 1	03:10	157 ± 8	206 ± 24	20 ± 10	230
Ketac™ Cem Maxicap™ 3M ESPE # 0033	16 ± 1	03:00	109 ± 17	252 ± 16	21 ± 7	230
Harvard™ Cement Richter & Hoffmann Shade: yellow # 2112400007 / 2111000009	22 ± 1	07:00	115 ± 10	218 ± 14	15 ± 1	563
Fuji I™ GC # 9905251	22 ± 1	03:15	164 ± 18	209 ± 17	8 ± 1	180
Fuji™ Luting GC Shade: yellow # 0003261	10 ± 1	03:15	101 ± 9	124 ± 4	11 ± 1	n.d.

Particle size distribution

	Mean particle size (d50) [µm]	Maximum (>98%) [µm]
Ketac™ Fil Plus	6 - 7	42
Ketac™ Cem radiopaque	ca. 2,5	12
Ketac Cem Aplicap	ca. 2,5	12
Ketac Cem Maxicap	ca. 2,5	12
Ketac Cem Easymix	ca. 2,5	12



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70200947649/03(10.2004)

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