ESPE

Product Dossier

Ketac® Molar Quick

Contents

1. Preface

The glass ionomers developed in the sixties and seventies have been successfully used in dentistry for around twenty years. This class of material is characterised by simple handling as well as self-adhesion, even to untreated dentine. Glass ionomers offer a translucency similar to porcelain materials and stand out due to their excellent biocompatibility. They are particularly suitable for conservative dentistry, but are also ideal for cementing indirect restorations.

Recently we have seen the development of so-called heavy-bodied "packable" glass ionomer cements, which are especially indicated as restorative materials for posterior teeth. One important product in this class of material is KETAC MOLAR. The improvement in the mechanical properties in comparison with conventional glass ionomer cements and the packable consistency make KETAC MOLAR ideal as a restorative material for the treatment of primary teeth and for extended fissure sealing, as well as for Class I restorations in the non-occluded area. Other sets of indications are semi-permanent Class II restorations and Class V restorations. With the new KETAC MOLAR QUICK it has been possible to reduce the setting time to a minimum. This material property in combination with a modified application nozzle results in economical usage particularly as a fissure sealant, in small posterior cavities and for patients with little time to waste.

2. Introduction

2.1 History of Glass Ionomers

The glass ionomers developed by Wilson und Kent in 1969 have meanwhile become a key item in every dental surgery. Over the years glass ionomers have been repeatedly modified and enhanced to meet the increasing demands being made on this class of material.

Scientific research into glass ionomers pursued two objectives: firstly, the aim was to develop an aesthetically appealing material for anterior teeth restorations and secondly, to improve the material properties to extend the areas of use to posterior teeth. The KETAC MOLAR product family is the result of consistent enhancement of ESPE's tried and tested glass ionomers. KETAC MOLAR is a heavy-bodied, metal-free glass ionomer, which has been specially designed as a restorative material for posterior teeth.

2.2 Motivation

As already mentioned, heavy-bodied glass ionomers are an extremely promising class of material.

Many scientific studies have shown that the strength of heavy-bodied glass ionomers may in some cases far exceed that of conventional glass ionomers. In particular, it has been possible to increase the abrasion resistance for this class of material.

KETAC MOLAR QUICK differs from KETAC MOLAR, which has already been used successfully for many years, by its shorter mixing and setting time and also in terms of the capsule geometry. KETAC MOLAR QUICK can be placed directly in the cavity due to the narrower design of the application nozzle on the Aplicap. This modification offers easier access to cavities subject to minimally invasive preparation and ensures a better view of the work field.

2.3 Indications

After many years of clinical use, KETAC MOLAR can be recommended for the following indications:

- primary teeth restorations
- Class I restorations
- fissure sealing
- semi-permanent Class II restorations
- core build-ups

Given the difference in setting times and the associated working time, the following recommendation can be made for indications in comparison with KETAC MOLAR APLICAP:

Table 1: Indication recommendation for KETAC MOLAR product family

	KETAC MOLAR QUICK APLICAP	KETAC MOLAR APLICAP
Core build-ups		X
Class I (small)	X	
Class I (large)		X
Class II (small)	X	
Class II (large)		X
Primary tooth restorations	X	

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Fissure sealing	X	

3. Chemical Background

3.1 General Overview

Heavy-bodied glass ionomers do not just result from the simple mixing of glass powder and polycarboxylic acid. As in the case of conventional glass ionomers, curing is due to the reaction between the polycarboxylic acid in the liquid and the reactive fluorocalcium aluminosilicate glass of the glass powder. Unlike conventional glass ionomers these cements are characterised by greatly increased abrasive stability.

3.2 Chemical Background

The curing of glass ionomers is the result of a complex sequence of chemical reactions in which water plays a key role. While in the first setting period the start of the reaction between the powder and the polycarboxylic acid depends on the presence of water as a solvent, in the subsequent setting period the glass ionomers are extremely sensitive to the ingress of water, but also to overdrying. The chemical processes involved in curing can be broken down into four stages.

1) Decomposition of glass structure:

One major prerequisite for the glass materials used is solubility in acids. While cross-linked silicates are attacked by virtually no acid, calcium aluminosilicate glass reacts even with a relatively weak polycarboxylic acid. This is due to the aluminium component of the glass materials. Aluminium is taken up into the cross-linked silicate and results in formally negative charging of the aluminosilicate. This makes the glass alkaline and susceptible to attack by both inorganic and organic acids. These negative charges are counterbalanced in the glass powder through alkaline or alkaline earth ions (see Fig. 1).

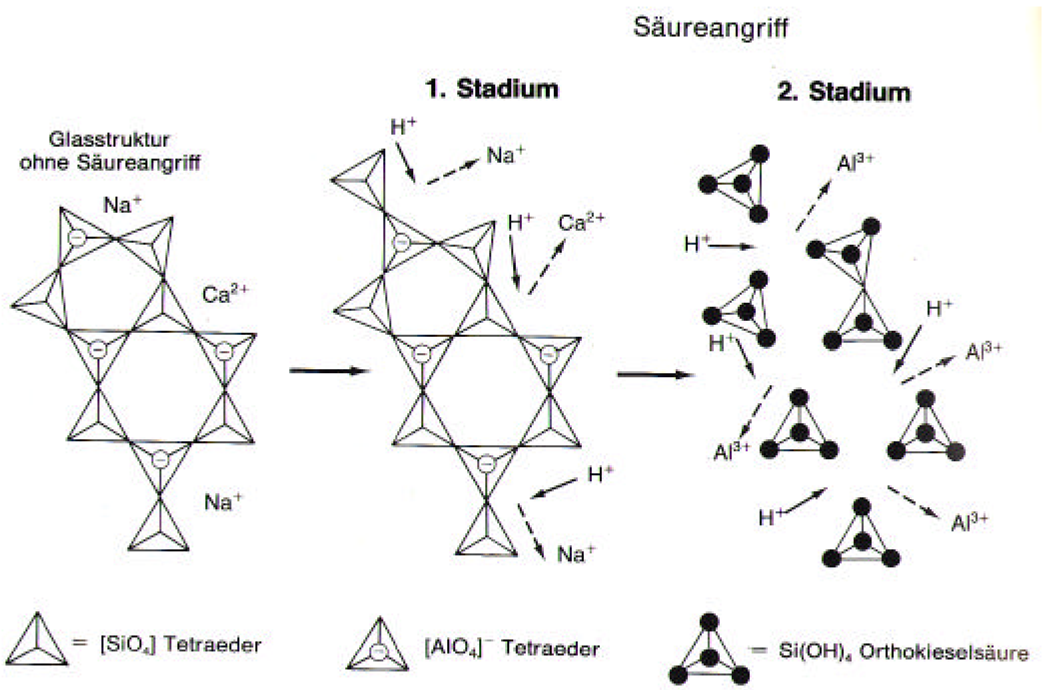


Fig. 1: Structure of an aluminosilicate
(Illustration: A.D. Wilson, J.W. McLean "Glasionomere", published by Quintessenz Verlag 1988, P. 26)

Key for diagram:

1. Acid attack
2. 1st stage
3. 2nd stage
4. Structure of glass before acid attack
5. $[SiO_4]$ tetrahedron
6. $[AlO_4]$ tetrahedron
7. $Si(OH)_4$ orthosilicic acid

In the first step the calcium and sodium ions are replaced by protons. In the next step all aluminium oxygen bonds are broken, thus producing orthosilicic acid.

2) Curing reaction

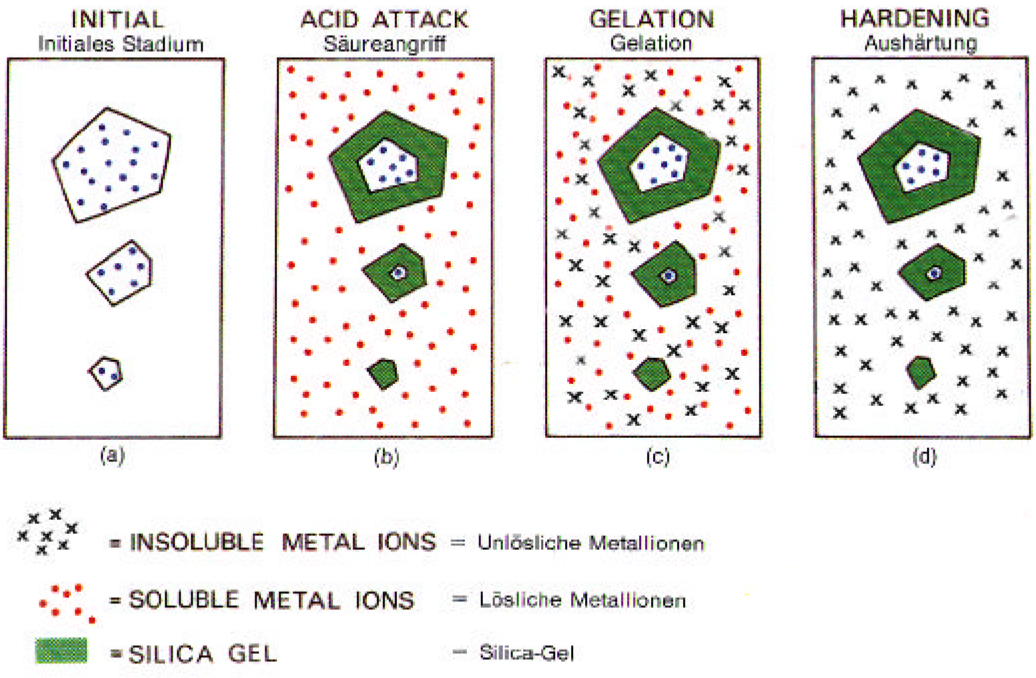


Fig. 2: Formation of silica gel on the surface of the glass
(Illustration: A.D. Wilson, J.W. McLean "Glasionomere", published by Quintessenz Verlag 1988, P. 45)

The acid attack takes place on the surface of the glass particles. This involves a heterogeneous reaction between a solid and a liquid. The resulting silicic acid reacts spontaneously with other silicic acid molecules under polycondensation to produce silica gel.

The ions previously firmly integrated in the glass are released and migrate into the aqueous phase of the cement. This effect can be observed, for example, in the release of fluoride ions from glass ionomers. The released cations react with the anions of the polycarboxylic acids to form water-insoluble polycarboxylates.

3) Effect of tartaric acid

To ensure a working time of sufficient length, tartaric acid is used as a complexation reagent for the detached metal ions. The complexation process occurring during the first setting period results in metal ions being temporarily removed from the cross-linkage with the polyanions. This reaction is a reversible process. In the subsequent setting stage the metal ions previously complexed become available for cross-linking again. This means that the setting process can be optimised for a procedure tailored to surgery requirements. The working time is increased, and the setting time reduced ("Snap-Set").

4.Operating Principle of an ESPE Capsule

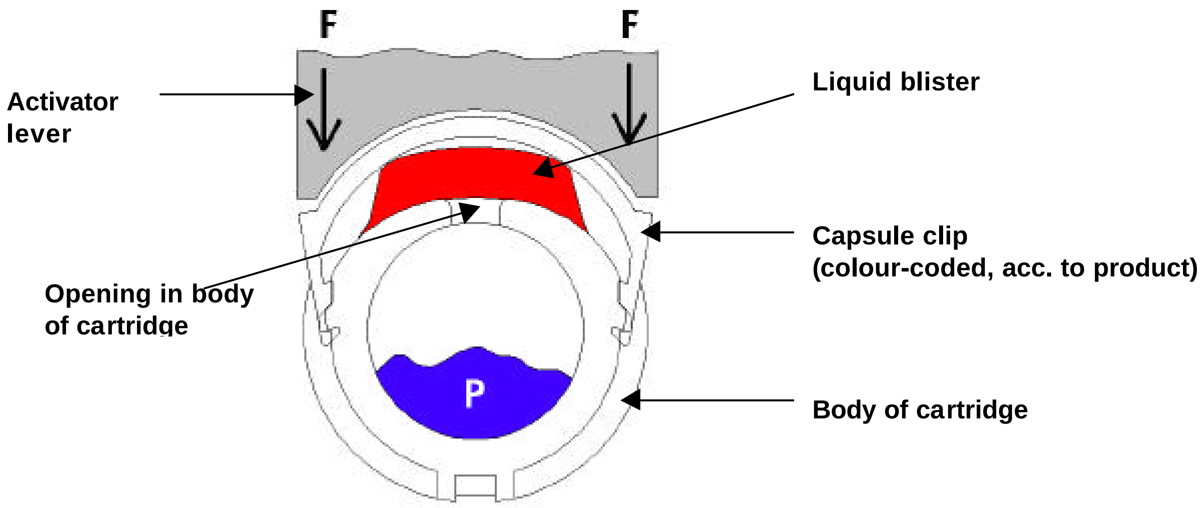
In an ESPE mixing capsule a powder and a liquid are mixed at a specific pre-measured and unchanging liquid to powder ratio (P/L) for application as a ready-to-use glass ionomer cement from the capsule directly in the patient's mouth.

To ensure an adequate shelf life the individual components are stored separately from each other. The powder is contained in a capsule cartridge. The liquid is stored in an airtight and gasproof foil blister that is located between the cartridge and a capsule clip.

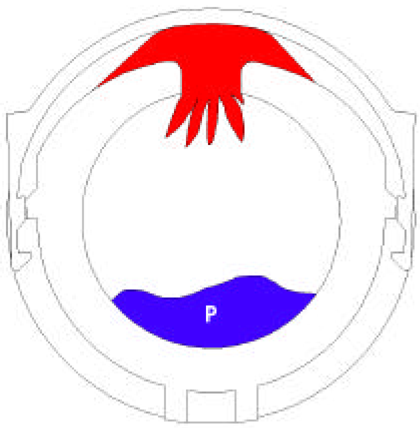
The two components must be initially blended in the mixing chamber of the cartridge prior to use. This process is known as activation. Special attention must be paid to the activation process particularly to ensure the required heavy-bodied consistency. An exactly predetermined liquid to powder ratio can only be achieved with the right handling of the activation unit, the so-called ESPE-capsule activator. This process functions as follows:

When the activator lever is pressed, the clip is forced towards the body of the cartridge via a slider. This forces the liquid blister against the body of the cartridge.

Cross-section through an ESPE Aplicap capsule

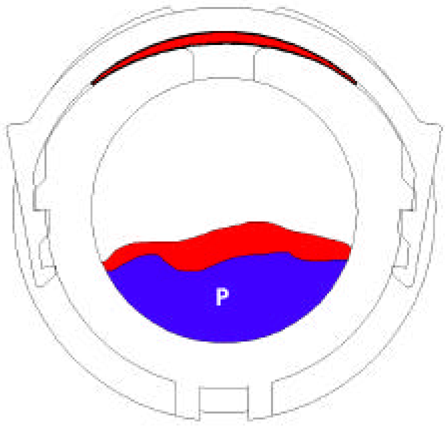


If sufficient pressure is applied, the liquid blister (red) bursts right over the opening provided for this purpose in the body of the cartridge and the liquid is squirted into the mixing chamber in the body of the cartridge. This is normally apparent from the abrupt reduction in resistance of the lever.



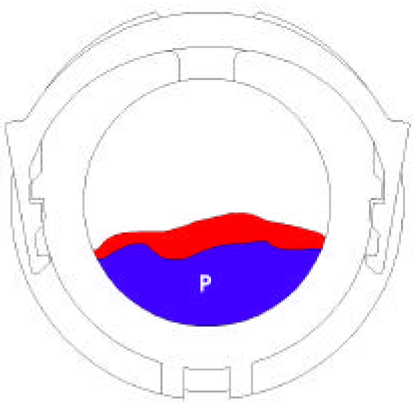
The liquid blister has burst at the start of activation and the liquid escapes.

However, the entire quantity of liquid required is not forced into the body of the cartridge at this stage. The activator lever has not reached its stop point on the metal bolt and the activation process is not yet complete.



The liquid blister moulds itself to the body of the cartridge when pressure is applied up to the final pressure point.

As this process involves a predetermined liquid to powder mixing ratio, virtually the entire liquid has to be forced out of the foil blister. This is achieved by pressing the activator lever down further until it makes contact with the metal bolt. This causes the clip and body of the cartridge to become slightly deformed. As a result the blister closely moulds itself to the body of the cartridge and the remaining liquid is forced into the cartridge. At the final pressure point the activator has to be held down for a minimum of 2 seconds to give the liquid sufficient time to escape from the blister. This also requires a certain amount of force, as for example when attempting to press the last of the toothpaste from the tube.



After holding down the activator for 2 seconds at the final pressure point virtually the entire fluid has escaped from the blister.

In this regard it is not recommended to perform the activation process when sitting down or even in a drawer as it is then scarcely possible to apply the pressure required.

After activation has been performed successfully, the capsule is placed in the mixing unit and removed after the specified mixing time. The ready mixed material can now be applied directly. If the steps required for activation and mixing of an ESPE capsule are followed closely, a very high working quality can be achieved for the ESPE glass ionomer.

5. Product Composition

Glass ionomers (polyalkenoate cements) consist of the combination of powder and liquid typical for dental cements. Polycarboxylic acids are used with conventional glass ionomers. The powder includes special reactive glass materials. The curing mechanism is an acid-base reaction between these glass materials and the polycarboxylic acid from the liquid.

5.1 Product Components

KETAC MOLAR QUICK is a dual-component, chemically cured restorative material on glass ionomer basis which is available in the capsule version (KETAC MOLAR QUICK APLICAP) permitting user-friendly direct application.

5.2 Constituents

The qualitative composition of the two components of KETAC MOLAR QUICK is shown in Tables 1-2.

Table 2: Composition of the powder in KETAC MOLAR QUICK

Ca,La,Al fluorosilicate glass
Pigments

The mean particle size of the glass materials contained in the powder of KETAC MOLAR QUICK is 2.7 µm. The grain size distribution shows that 90% of all particles are smaller than 9 µm and 10% of all particles smaller than 1 µm.

Table 3: Composition of the liquid in KETAC MOLAR QUICK

Polycarboxylic acid
Tartaric acid
Water

The liquid is preserved with benzoic acid. The powder to liquid ratio is 3.4:1.

6. Test Results

6.1 Material Properties

The setting process described for glass ionomers in the above chapter results in virtually contraction-free curing for this class of material. This means that the material is only subject to minimal stresses which could cause the formation of marginal gaps at the cavity margins. For this reason no additional complicated bonding agents have to be used with glass ionomers, as are normally required with polymerisable products. As a result there is no need for high bond strengths at the enamel and dentine to counteract the setting contractions.

Furthermore, glass ionomers have a thermal expansion coefficient similar to that of teeth. Therefore, no additional stress is produced on the adhesive bond between the restorative material and hard tooth substance due to major differences in temperature. These two material properties mean that an optimised clinical marginal behaviour can be achieved for glass ionomers without the necessity for high bond strengths.

Another important material property of glass ionomers is their resistance to abrasion. When using conventional glass ionomers, the abrasion and erosion of the restoration observed is a frequent shortcoming, particularly in the case of posterior teeth. Intraorally glass ionomers are subject to chemical and mechanical degradation. The result is the formation of "negative ledges" at the point of contact between the restoration and tooth. Besides the properties described above, a high abrasion resistance is thus desirable to ensure a restoration which is satisfactory in both aesthetic and clinical terms.

6.2 Physico-technical Data

The physical properties of KETAC MOLAR QUICK are shown in Table 3. The data are based on specification test procedures of the International Standards Organization (ISO) and the German Institute for Standardization (DIN).

Table 4: Mechanical properties of KETAC MOLAR QUICK and Fuji IX fast

	KETAC MOLAR QUICK	**Fuji IX fast**	**KETAC MOLAR**	**Fuji IX**	**Test standard**
Setting time	less than 2 min	2:00 min	2:15 min	2:20 min	ISO 9917
Compressive strength	210 MPa	230 MPa	230 MPa	230 MPa	ISO 9917
Flexural strength	30 MPa	30 MPa	30 MPa	30 MPa	ISO 4049
Surface hardness	490 MPa	340 MPa	450 MPa	340 MPa	DIN 53456
Radiopacity	2 mm Al	2.7 mm Al	2.7 mm Al	3.3 mm Al	ISO 4049

7. Summary

The glass ionomers developed in the sixties and seventies cover a wide spectrum of use. Heavy-bodied glass ionomers were developed due to the low abrasion resistance of conventional glass ionomers. In comparison with conventional glass ionomers this class of material offers a number of positive properties which make them ideal for a large number of clinical areas of use.

KETAC MOLAR QUICK is characterised by an optimised setting time. This benefit along with the small application nozzle mean that KETAC MOLAR

QUICK is ideally suited for use in small posterior cavities, as a fissure seal-ant material and for patients with little time to waste.

8. Handling Instructions

KETAC MOLAR QUICK APLICAP is available in three different shades. The quantity dispensed from a capsule of KETAC MOLAR QUICK is at least 0.25 g.

KETAC MOLAR QUICK APLICAP should be activated for a minimum of 2 seconds prior to mixing and then mixed for 10 seconds in the high-frequency mixer Capmix®. In the new ROTOMIX - which produces a void-free and even more homogeneous mix - the mixing time is 8 seconds.

After insertion in the Aplicap applier, KETAC MOLAR QUICK APLICAP can be placed directly in the cavity. To increase adhesion, the walls of the cavity should be treated with KETAC CONDITIONER.

Clinical Procedure

The initial situation involves two composite restorations at 14/15 in need of renovation, as is clearly shown by the dark discoloration of the restoration margins.

Figure 3: *Initial situation: restorations at teeth 14-15 in need of renovation.*

Following removal of the old restorations and secondary caries, two small cavities in two surfaces require treatment. When preparing the cavities special attention was paid to removing the margins of the composite restorations which taper off thinly (bevelling). The cavities shown here are so small that it would be difficult to ensure that the glass ionomer cement is applied free from air voids using conventional capsule preparations (KETAC MOLAR APLICAP). This example shows the advantage of the KETAC MOLAR QUICK APLICAP capsule system with its long thin application nozzle (based on the materials KETAC-CEM and KETAC-FIL PLUS).

Figure 4: *Fully prepared cavities 14 od, 15 mo und d. Margins which taper off thinly were avoided. A minimally invasive preparation was used for distal 15. A CaOH preparation was applied to 14.*

However, before placement of the restorative material a number of steps need to be undertaken. The insertion of a rubber dam is not normally required. With approximal cavities, as in this example, it is essential to use matrix bands. Metal bands are the preferred option in this case as the restorative material does not have to be light-cured. At all events it should be ensured that after restoration the approximal contact is strong enough. If this is not possible with two restorations placed simultaneously, it may be necessary to place the restorations one after the other.

Other steps are:

- maintaining a relatively dry environment (e.g. with cotton wool rolls)
- lining of areas close to the pulp with a CaOH preparation (see Fig 4.)
- thorough disinfection of the cavity (70% alcohol)
- conditioning using Ketac® conditioner (25% polyacrylic acid, allow to work for 30 s)

Figure 5: *Cavities before conditioning. For better adaptation of the matrix bands an interdental wedge has been used.*

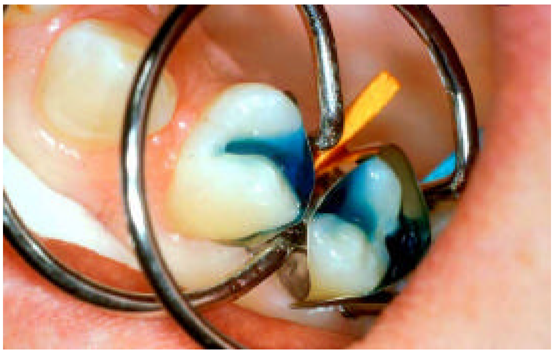


Figure 6: *Conditioning of cavities using KETAC CONDITIONER*

When restoring the cavities the capsule design of KETAC MOLAR QUICK APLICAP is very helpful. Due to the more liquid consistency of the material compared with KETAC MOLAR APLICAP it was possible to make the application nozzle of the capsule more slender. This means that the cavities in this example can also be restored under pressure and free from air voids.

The material shows excellent flowability even with the smallest of cavities (distal 15).

Figure 7: *Restoration of cavities using KETAC MOLAR QUICK APLICAP. The thin application nozzle can be used to apply the restorative material directly in the cavity.*

After approx. 1 min the material can be packed to a limited extent; most of the excess material can also be easily removed at this stage. To protect the restoration from moisture during the setting period, it is recommended to line the restoration with KETAC GLAZE (or a light-cured bonding material).

Figure 8: *In the plastic phase KETAC MOLAR QUICK APLICAP can be packed to a limited extent; it is also simpler to remove the excess material at this stage than when cured.*

After finishing and polishing, stable restorations with a high marginal integrity can be seen. The colour match is very good for a glass ionomer cement. Slight variations in colour facilitate finishing of the restoration and possible removal at a later date. Particularly when removing a restoration, a marked loss of tooth substance is accepted with composite restorations of a better appearance.

Figure 9: *Completely finished KETAC MOLAR QUICK restorations.*

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