

3M ESPE

Protemp™ 3 Garant™

Temporization Material

Technical Product Profile



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Preface

Temporary crown and bridge restorations are an indispensable yet demanding interim solution which call for high-quality materials and great care on the part of the dentist.

Due to the clinical and technical procedures involved, crown and bridge restorations require several distinct treatment phases for completion. Thus, a temporary restoration is needed for the interim phase. In the past, the functional aspects of a temporary restoration predominated, while today's materials also have to cater to the increased demands placed on aesthetics and economy – a difficult balance to achieve. The rapid evolution of aesthetic restoration materials such as ceramics and composites has been accompanied by improvements of temporary materials. Currently, a large number of suitable temporary materials are available for the fast and effective restoration of prepared teeth.

As early as 1968, ESPE pioneered the development of composite-based temporary crown and bridge materials. Over time, ESPE's product development yielded continuously improved materials offering superior mechanical properties, reduced polymerization heat as well as a more precise fit and color stability.

With 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material, a further milestone has been achieved. This class of material features greatly improved fracture resistance without any compromises in terms of the tried and tested product benefits. This innovation is rounded off by a new cartridge system with enhanced handling characteristics.

Also available for the Protemp 3 Garant system are the 3M™ ESPE™ Protemp™ 3 AddOn materials. The Protemp 3 AddOn material is a low viscosity, visible light-cured flowable composite used for customizing, shape correction and repair of the Protemp 3 Garant temporization material. The Protemp 3 AddOn material is easily added or bonded to previously cured Protemp 3 Garant temporization material. The Protemp 3 AddOn materials are precisely matched to the Protemp 3 Garant temporization material shades. The Protemp 3 AddOn material is available in an easy to use syringe system.

*Table 1.
Composite-based temporary
crown and bridge materials
available from 3M ESPE*

1968	Scutan (Composite with organic PMMA fillers)
1982	Protemp (Composite with inorganic glass fillers)
1989	Protemp II (Improved handling)
1994	Protemp Garant (Automatic cartridge system)
1997	Protemp II/ Protemp Garant (New colors) 3M™ ESPE™ Iso-Temp™ Temporary Material (multiphase setting) Protemp Garant (New formulation)
2001	Protemp 3 Garant (Substantially increased resistance to fracture)

Introduction

The functions which a temporary restoration must fulfill are wide-ranging and demanding. They basically correspond to those of the final restoration, albeit only for a limited period of time. This also applies in principle to teeth whose pulp is dead, while here the biological relevance of dentine contact can be disregarded. Certain compromises in terms of the aesthetic impression are both normal and acceptable, although this aspect is becoming increasingly important from the patient's viewpoint. Where problematic adjustments regarding aesthetics, phonetics and masticatory functions are concerned, a restoration which can be modified within certain limits is of diagnostic and prognostic value alike in assessing the planned final restoration.

The quality of the restoration not only depends on the quality of the materials provided, but also on the workmanship of the operator or laboratory and cooperation on the part of the patient with regards to hygiene.

The following basic requirements can be listed for temporary restorations:

- For the success of the subsequent prosthetic restoration, it is essential for the prepared teeth to maintain or re-establish their position relative to adjacent teeth and antagonists, and for a temporary restoration to offer sufficient resistance to masticatory forces (diagnostic and masticatory functions).
- To ensure protection for periodontal regions, high requirements have to be stipulated for exact marginal fit, polishability and biocompatibility to rule out consequential damage to the gingiva and bone.
- Restorative dentistry calls for materials which represent no risk to the dentin during treatment and avoid further irritation of the pulp (pulp protection function and anti-caries prophylaxis).
- To ensure up-to-date oral prophylaxis, it is important to maintain hygiene: where possible, the patients should have the opportunity to clean their temporary restorations like normal teeth.
- For the patient, the appearance of the restoration plays an important role, i.e. aesthetics and satisfactory phonetics. In a word, minimization of the physical and psychological impairment while the restoration is in place.
- For the dentist, who is called on to produce a high-quality, perfect and modern restoration, benefits in terms of hygienic handling, less demanding technique and rapid completion of treatment are also becoming increasingly vital.

History

The oldest group of polymer-based direct temporary materials are the acrylic MMA/PMMA resins. Here, PMMA microbead powder is mixed with monomer liquid and bonded with polymerized methyl methacrylate. The importance of these materials continues to decline, not lastly due to their numerous shortcomings. Their high level of monomer release should not be underestimated, in particular when regarding the application to the freshly prepared tooth using the direct technique. A highly exothermal reaction during setting requires the early removal of the temporary restoration from the preparation. This predisposes to the problem of unsatisfactory fit due to the subsequent polymerization shrinkage. However, the low price and good color stability guarantees PMMA materials a limited market share, albeit with a declining tendency.

Materials made of monofunctional acrylate monomers with a higher molecular weight have been developed to eliminate some of the disadvantages of polymethyl methacrylate compounds. This also involves powder/liquid systems which have to be mixed by hand and consist, for example, of mixes of polyethyl methacrylate powder and i-butyl methacrylate liquid. A lower setting temperature and, in comparison with PMMA materials, slightly enhanced mechanical strengths are offset by very poor aesthetics and a low resistance to masticatory forces. In addition, these restorations are attacked by cements containing eugenol, something which is of disadvantage particularly in the field of temporary restorations.

The newest and also most successful class of material on the market is the group of bisacrylate composites. Comparable with composites used for definitive restorations, these materials consist of an organic matrix and inorganic fillers. Monomers such as bisphenol-A-glycidyl methacrylate (bis-GMA), triethylene glycol dimethacrylate (TEGDMA) or similar monomer systems derived from Bowen resin are used in the organic polymer matrix. The inorganic fillers account for approximately 40 per cent by weight in the paste. The introduction of the bisacrylate systems for temporary restorations resulted for the first time in the availability of materials with improved mechanical properties, a lower setting temperature and reduced polymerization shrinkage as well as good color stability and polishability. When the hand-mix versions (paste/paste) were supplemented by automix-cartridge systems in the early 90s, it also became possible to satisfy the demands for simple, clean and fast handling. However, the fracture resistance of these materials still merits improvement. Unfortunately, high mechanical strength also comes hand in hand with brittleness. In daily dental practice, this manifests itself in fractures or chipping at the margin during finishing or masticatory stresses: an unpleasant and troublesome phenomenon for dentists and patients.

With 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material, a further milestone in the field of temporary restorations has now been reached. A material with dramatically improved resistance to fracture and very low fracture rates under load is available today.

Motivation

With a U.S. dollar market share of 57%, the bisacrylate composite materials have firmly established themselves with practitioners in the field of temporary restorations – due to their favorable characteristics in terms of mechanical strength, comparatively low setting temperature and polymerization shrinkage as well as good color stability and polishability, while at the same time offering handling advantages in the operator.

There are calls for improvement for the resistance to fractures and fracture rates. This improves the quality of life for the patient while the restoration is in place and reduces troublesome repair work by the dental staff. The demand for temporary restorations with greater fracture resistance is also reflected in a large-scale market study. Here, a low fracture rate and simple correction and repair were described as the most important criteria for a temporary restoration material. In addition, it should also ensure a low exotherm during setting, high levels of precision and fit as well as good biocompatibility.

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material has been developed to meet these needs. An innovative monomer system combines high flexural strength and high flexural resistance (characteristic value: elastic modulus) with high elongation at break which permits brief deformation yet guarantees complete recovery. This results in a matrix which can accommodate brief peak forces without fracturing. Stable occlusion, reliable proximal support and protection of the periodontium and abutment teeth are achieved by the material's high mechanical strength.

An optimized and also newly developed initiator system is responsible for ideal setting. The ideal polymerization process during the handling timescale must firstly provide for an elastic phase of sufficient length but then also result in ultimate hardness of the product as quickly as possible, without a high exothermal reaction and marked polymerization shrinkage.

Lastly, material characteristics such as surface finish, polishability, aesthetics and stability of the matrix filler system are achieved by sophisticated filler technology. This is also reflected in color and dimensional stability while the restoration is in place.

One basic prerequisite for the development of Protemp 3 Garant temporization material was therefore that the key feature of increased resistance to fracture and a major reduction in the fracture rate under clinical conditions should not be achieved at the expense of the other material characteristics. On the contrary: the benefits already offered by modern bisacrylate systems over monofunctional acrylates were to be optimized even further. That this has succeeded is shown by the results of intensive cooperation with a large number of universities throughout the world. The subsequent sections will cover a selection of the results on material properties and user experience.

Indications

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material is a temporary crown and bridge material for use with the direct technique for:

- crowns
- bridges
- inlays
- onlays
- veneers
- lining of prefabricated crowns

It is compatible with all impression materials. Also suitable are laboratory-made templates or strip crowns for single tooth restoration.

If required, anatomical remodeling can naturally be performed with Protemp 3 Garant temporization material after building up the intended additions on the model in wax and capturing them. If an anatomical change in shape is required, the situation can of course also be shown waxed up on the model and then realized using Protemp 3 Garant temporization material. In addition, it is also very easy to carry out individualization with 3M™ ESPE™ Protemp™ 3 AddOn Material both in terms of shape and color at the laboratory, or directly at the chairside, opening up a further range of modeling options.

Chemical Background

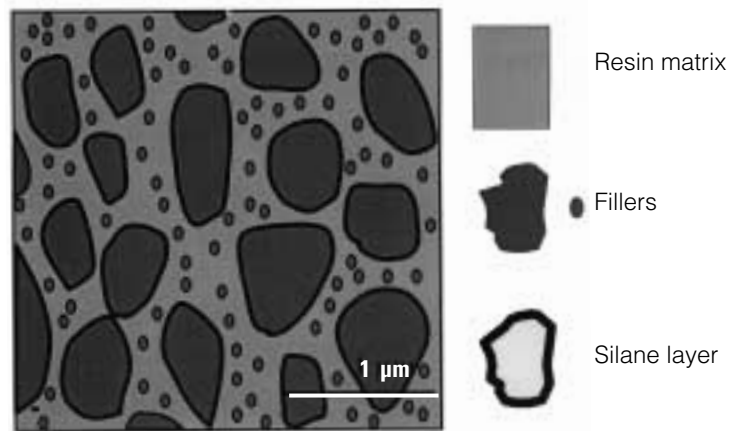
The Chemistry of Composite-Based Temporization Materials

A dental resin is made up of the following main constituents (see also Figure 1):

- resin matrix/monomers
- initiators
- silanized fillers

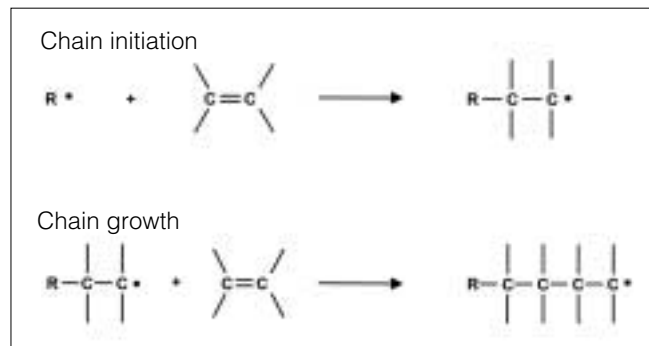
The monomers contained in the organic matrix become bonded to each other through a radical polymerization reaction.

Figure 1.
Structure of a composite



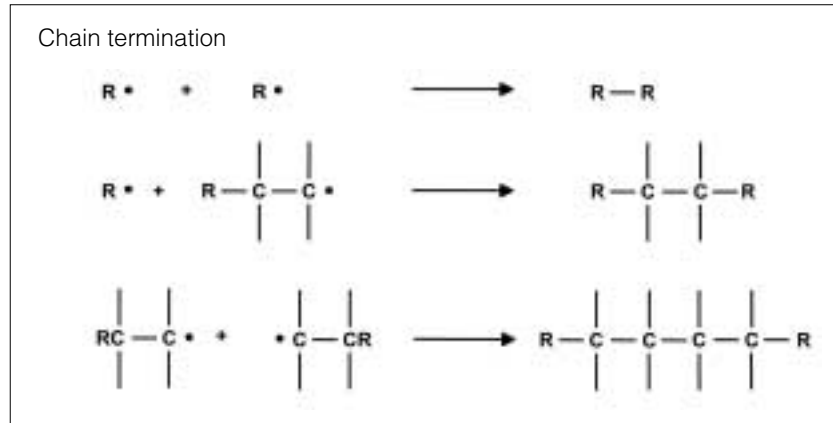
With self-curing materials, this occurs when the initiator components come together during mixing of the base paste and catalyst and react with each other in a redox reaction. It produces a radical R^\bullet , which is now capable of attacking the double-bond of an acrylate group and itself generating a radical. This process is called a chain initiation reaction (see Figure 2).

Figure 2.
Steps involved in the polymerization reaction



The chain growth reaction will continue as long as a free radical encounters a double-bond. As the chain is extended – this process represents actual polymerization – molecules of ever-increasing size are formed. Only when two radicals directly encounter each other are they recombined and the reaction finishes in a chain termination reaction (see Figure 3). This stops further growth of the chain.

Figure 3.
Steps involved in the
polymerization reaction



If a polymer matrix solely consists of monofunctional low-molecular monomers, as is the case with MMA/PMMA materials, only linear chainlike polymers can be formed (see Figures 3 and 4). Three-dimensional interlacing is only possible through physical looping of the individual polymer strands, and the resulting framework is not very stable. Major disadvantages of polymethyl methacrylates and their higher homologues can easily be concluded from this situation: high polymerization shrinkage, low mechanical stability and relatively high residual monomer detachment. This is also associated with very high elasticity which is however irreversible, taking the form of “cold flow.” This means that the material yields under load but does not recover when the load is removed. The attachment apparatus and the periodontium can be traumatized.

Figure 4.
Polymerization of
methacrylate monomers
into polymethyl
methacrylate

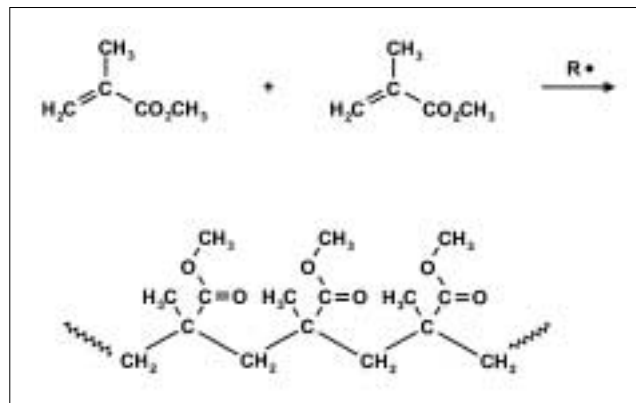
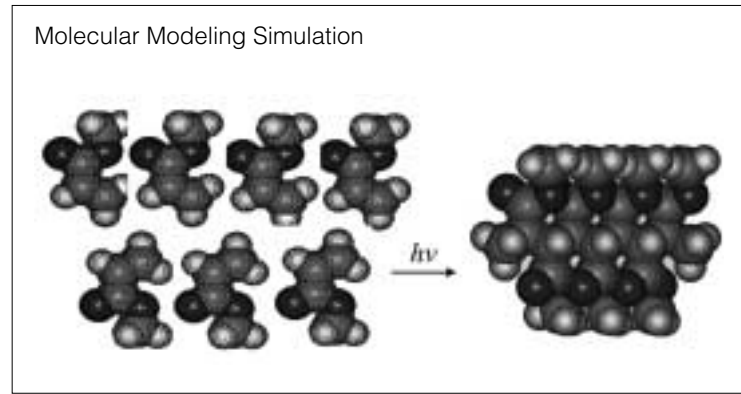


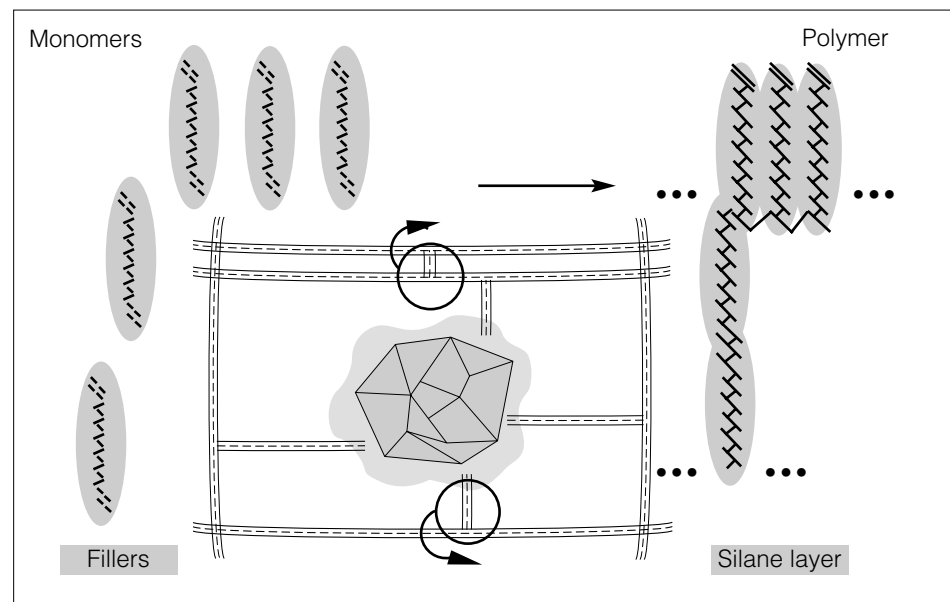
Figure 5.
Polymerization shrinkage



The situation is completely different for bisacrylate composites. Here, the monomers are bifunctional, i.e. they contain two double-bonds capable of reacting. Bisphenol-A-glycidyl methacrylate (bis-GMA), triethylene glycol dimethacrylate (TEGDMA) or similar monomer systems are frequently used. 3M ESPE utilizes modified Bowen resins which correspond to derivatives of the bis-acryl compounds that have been rendered hydrophobic. This provides for a major reduction in the water absorption of the materials; the dimensional stability while in place is also improved and discoloration is less frequent than with the other systems on the market (see Figure 5).

The multiple functionality of the monomers already mentioned above ensures the formation of a three-dimensional network, with the structure now being fixed by chemical bonds (see Figure 6).

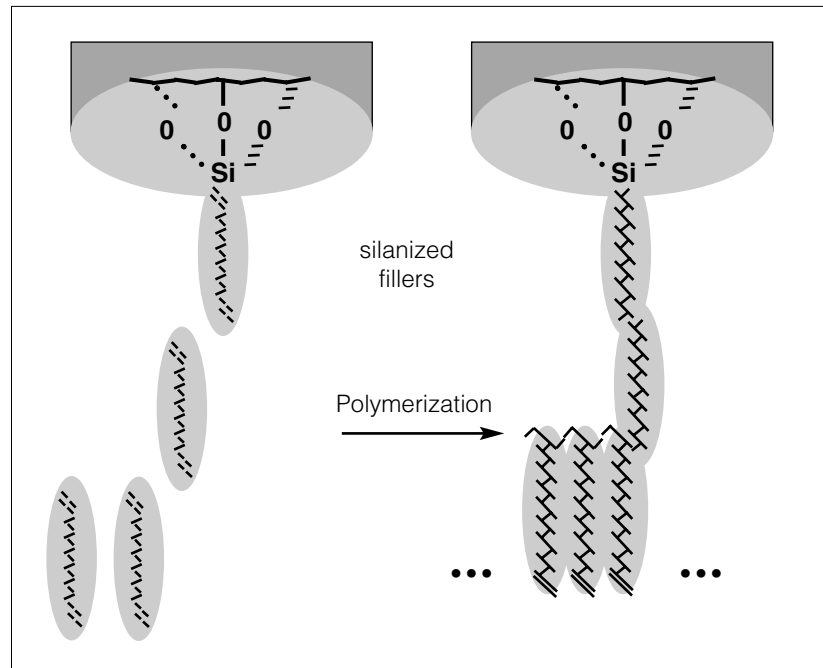
Figure 6.
Formation of
a polymer network



The incorporation of the inorganic fillers in the organic matrix is also a chemical process when the fillers are silanized as with 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material (see Figure 7). This produces a mechanically stable composite material which is wear-resistant, radiopaque and polishable.

In addition, polymerization shrinkage is greatly reduced in comparison with the filler-free MM/PMMA materials. One direct clinical result of this is the good precision of fit of the temporary restorations.

Figure 7.
Chemical incorporation
of fillers in the matrix



Special Characteristics of 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material

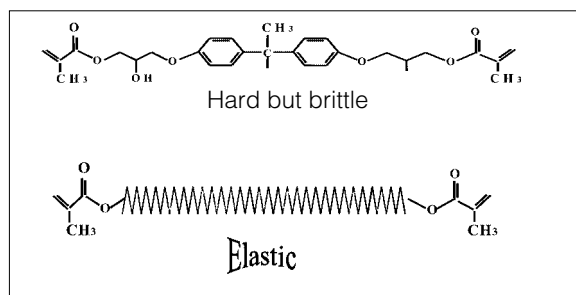
In addition to the favorable characteristics of a composite as already achieved for 3M™ ESPE™ Protemp™ Garant™, the innovative new development of Protemp 3 Garant temporization material also has a few other special features to offer.

At the outset it was mentioned that there is a strong demand for less brittle composites, i.e. materials with a greater fracture resistance but still offering high mechanical strength, in particular for the production of temporary restorations. Another objective is to increase edge strength and marginal stability to achieve thinly tapered and exactly fitting margins without having to expect chipping while finishing and during the wearing period.

In material scientific terms, this means that it was necessary to find a material which permits limited deflection that is higher than for standard composites, but does not mimic to the behavior of MMA/PMMA materials, which can undergo great deflection but do not recover after-wards. At the same time high flexural strength and high flexural resistance (characteristic value: elastic modulus) are required to relieve the stress on the periodontia. To be recommended are resins with high tensile strength which withstand high stresses until fracture and can also tolerate brief deformation due to high elongation at break while at the same time offering a high elastic modulus.

To cater to this characteristics profile, 3M ESPE has developed a completely new monomer system. It has succeeded in striking a balance between high mechanical strength and limited elasticity of the resulting composite material. For this purpose, monomers were synthesized which do not possess a rigid intermediate chain, as in the case of bis-GMA homologues, but are already flexible in themselves (see Figure 8). Incorporation in the co-monomer matrix and bonding to the fillers takes place, as described earlier, via methacrylate units.

Figure 8.
Flexible chain of monomers
in the new monomer system



It was now possible to reduce the three-component initiator system used for Protemp II to two components. This involves a highly complex chemical system which provides high storage stability, steady setting behavior and color stability. As an indirect positive effect, the inhibition layer has been greatly reduced; the dentist will immediately appreciate this when finishing temporary restorations. Another important clinical aspect is a marked reduction in the generation of heat during the setting of Protemp 3 Garant temporization material.

Lastly, the Protemp 3 Garant temporization material formulation also includes new filler technology. The glass particles used are even finer than before and guarantee a smooth surface structure and good polishability (average particle size < 0.7 μm).

Individualization and Supplementation using 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material

When producing temporary restorations there is sometimes a requirement for simple individualization. Both the color adaptation and anatomical changes may play a role here.

Protemp 3 Garant temporization material has also been optimized in this regard. On the one hand, Protemp 3 Garant temporization material can be used as a supplementation material at any time. The option of using the flowable composite 3M™ ESPE™ Protemp™ 3 AddOn Material, for finishing work lends even more flexibility. Protemp 3 AddOn material used in combination with Protemp 3 Garant temporization material only requires a roughened surface; the additional use of a bonding agent is not necessary.

In summary, it may be said that Protemp 3 Garant temporization material represents a new generation of temporary restoration materials. All components – the organic matrix, initiator system and inorganic fillers – have undergone improvements. The result is an innovative material that caters perfectly to the requirements of both dentist and patient.

Product Composition

Product Components

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material is a two-component paste/paste system which is available in a new double-chamber cartridge (3M™ ESPE™ Garant™ 2 Dispenser). The mixing ratio of the base paste to the catalyst paste is 10:1, and mixing is carried out automatically using a dispenser.

With the Garant 2 dispenser, more material can be dispensed in the same amount of time. The separate cartridge openings prevent cross-contamination of the base paste and the catalyst. A color coding system offers additional safety.

Constituents

The qualitative composition of Protemp 3 Garant temporization material is listed in Table 2.

Protemp 3 Garant Temporization Material

Table 2.
Composition of base
paste and catalyst paste

Composition	
Base paste	Catalyst paste
Dimethacrylate	Softener
Strontium glass powder	Strontium glass powder
Silicic acid	Initiators
Initiators	
Diacrylate	
Stabilizers	
Synthetic resins	
Pigments	
Dyes	

Physical Properties

Material Properties

Besides sheer mechanical strength, the clinical success of a temporary restoration also greatly depends on physical parameters such as deflection at break, elongation at break and fracture resistance. These indicators provide information about the resistance to fracture and the fracture rate of the material. A mastication simulator or the edge strength test provide important information on a material by simulating clinical conditions.

Examinations focusing on accuracy of fit, polishability and color stability offer further key data about the product.

Since the beginning of 2000, a wide range of scientific studies have been carried out to ascertain the performance offered by 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material. In the subsequent sections, we will review the numerous material studies.

Long-Term Strength

M. Rosentritt, Dr. R. Lang, Dr. M. Behr, Prof. G. Handel, University of Regensburg

A mastication simulator was used to gain experience regarding long-term strength under thermocyclical and mechanical loads. In addition, the resistance to fracture of the materials was also tested.

In each case, the study used 10 three-unit bridges, which were fixed to molar preparations made of CoCr metal with periodontal positioning. Preparation involved the creation of a shoulder approximately 1 mm in size.

The test arrangement in the mastication simulator corresponds closely to the situation in the mouth and thus allows accurate forecasts to be made regarding performance under surgery conditions even at the stage of in-vitro testing.

Figure 9.
Resistance to fracture after 24 hours and after mastication simulation + thermocycling

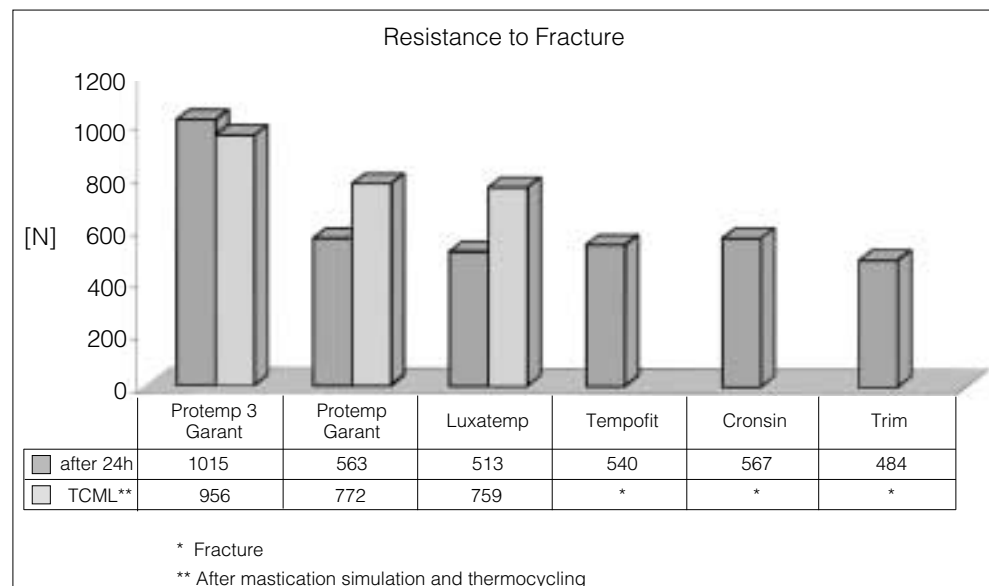


Figure 10.
Fracture after
mechanical cycles

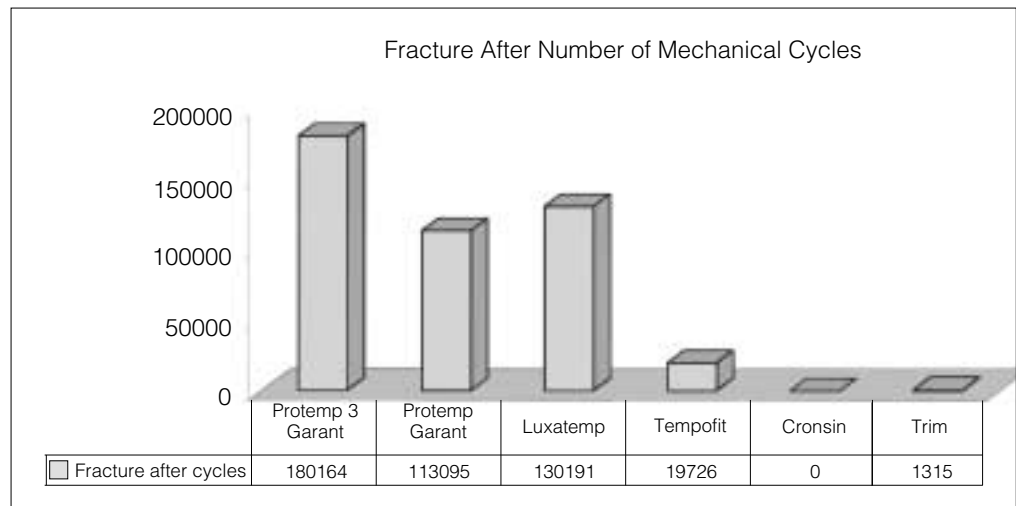
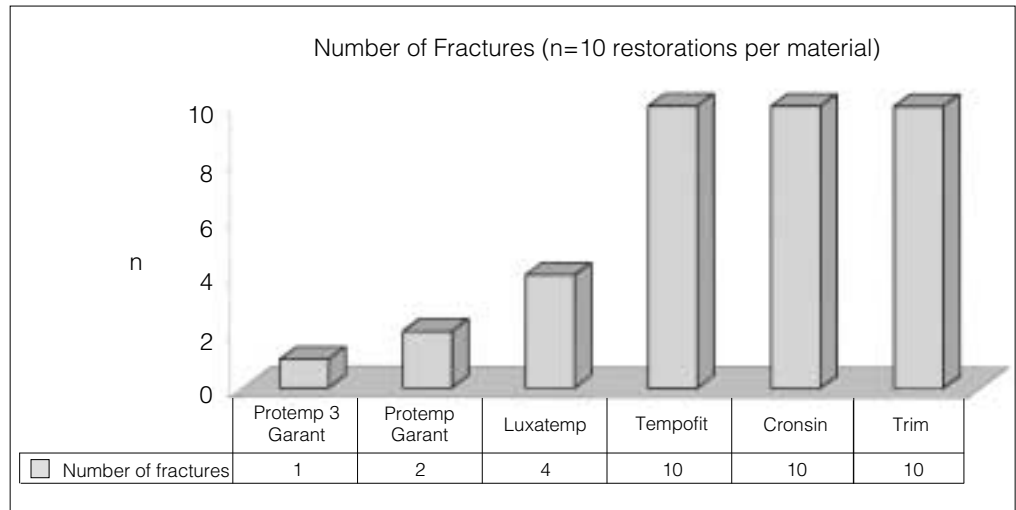


Figure 11.
Number of fractures with a
total of 10 inserted bridges
per material



3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material showed the highest resistance to fracture and also the lowest fracture rate of all materials tested. The low-molecular acrylates all fractured while subjected to the mechanical and thermal loads (Figure 9).

The mastication simulator provides initial indicators for the outstanding performance under surgery conditions and superiority of Protemp 3 Garant temporization material in comparison with its predecessor product, which proved its worth over many years. In addition, the force required to break a three-unit bridge surpasses the values of the competitor materials. Protemp 3 Garant temporization material is the only material with which just one out of the 10 bridges tested fractured under the mechanical load of more than 480,000 cycles. Furthermore, this fracture also happened after the largest number of masticatory cycles (n = 180164) (Figure 10).

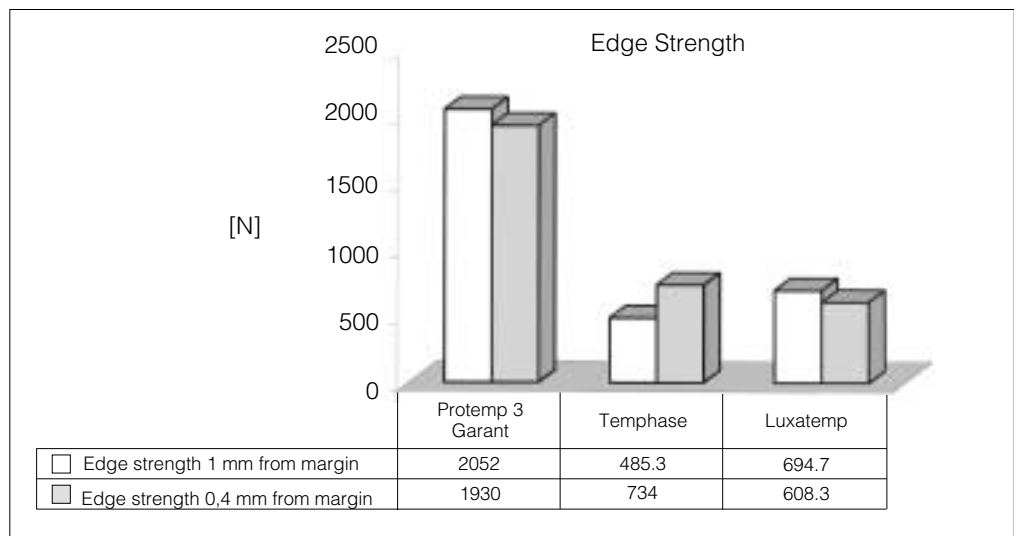
Edge Strength

Prof. D. Watts, University of Manchester

Another aspect contributing to the resistance to fracture is edge strength. In a test arrangement developed by the University of Manchester, force was applied near the edge of the test specimen (1mm thick). This allows the clinically relevant marginal strength of a temporary restoration to be simulated. Thin margins are particularly at risk from chipping when an interim restoration is undergoing finishing or being worn in the patient's mouth.

Force was applied at distances from 0.4 mm to 1.00 mm from the edge (in steps of 0.1 mm) after 1 month of storage under humid conditions at 37°C. The mean data are shown in Figure 12.

Figure 12.
Edge strength of a test
specimen 12 mm x 2.5 mm



3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material clearly stands out from the other composite materials tested. The edge strength of Protemp 3 Garant temporization material is significantly greater than that of Temphase and Luxatemp.

Other Mechanical Strength Properties

Prof. D. Welker, Dr. G. Rzanny, Dr. R. Göbel, University of Jena

Characteristic data which is easily accessible and routinely available, such as flexural strength and the elastic modulus, also provides basic information about the stability of a material. It is an indication of strength and resistance to deflection. High strength should not, however, be accompanied with brittleness, which can make the material susceptible to fracture. Pronounced elasticity combined with complete recovery after removal of the load is desirable to absorb peak forces without fracture or splintering of the restoration. Tensile strength and elongation at break may indicate the load and the tolerated level of deformation until fracture.

Figure 13.
Flexural strength as measured in the 3-point bending test

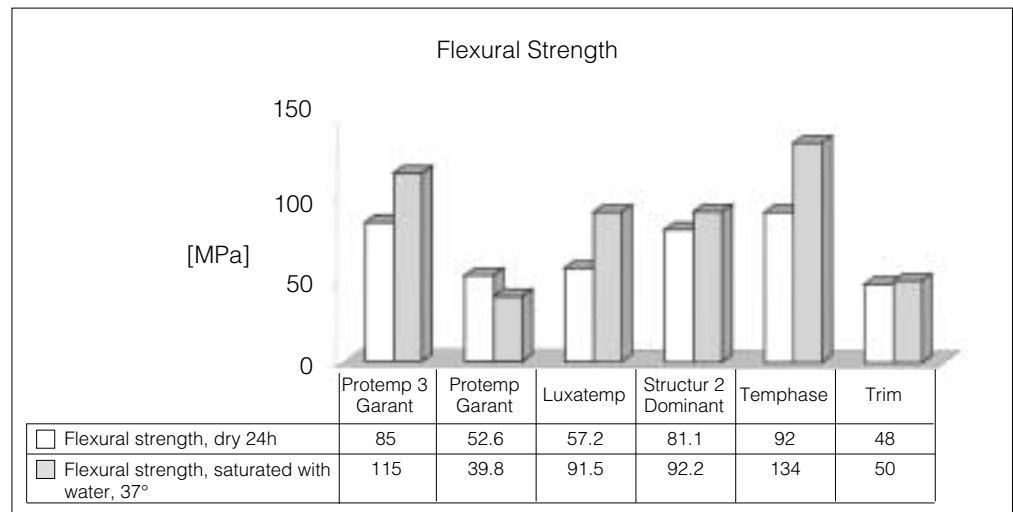


Figure 14.
Deflection as measured in the 3-point bending test as per DIN 53452

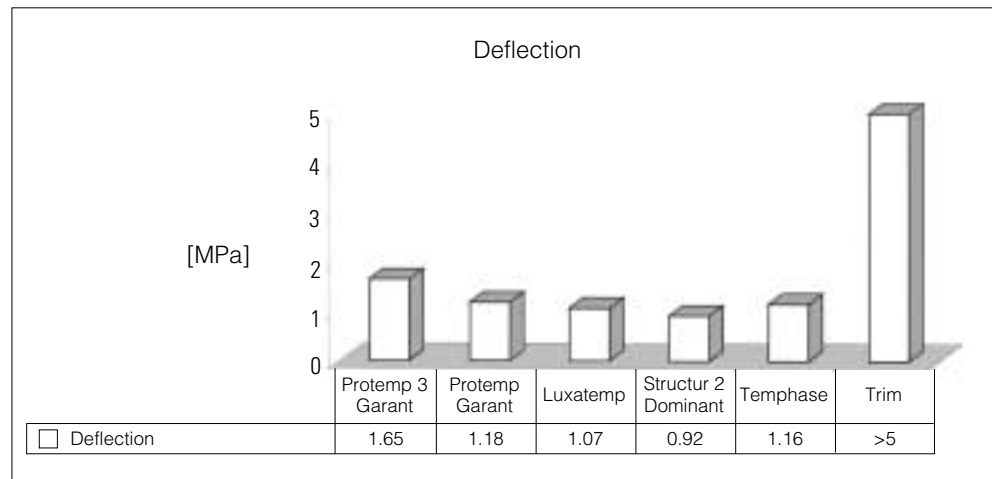
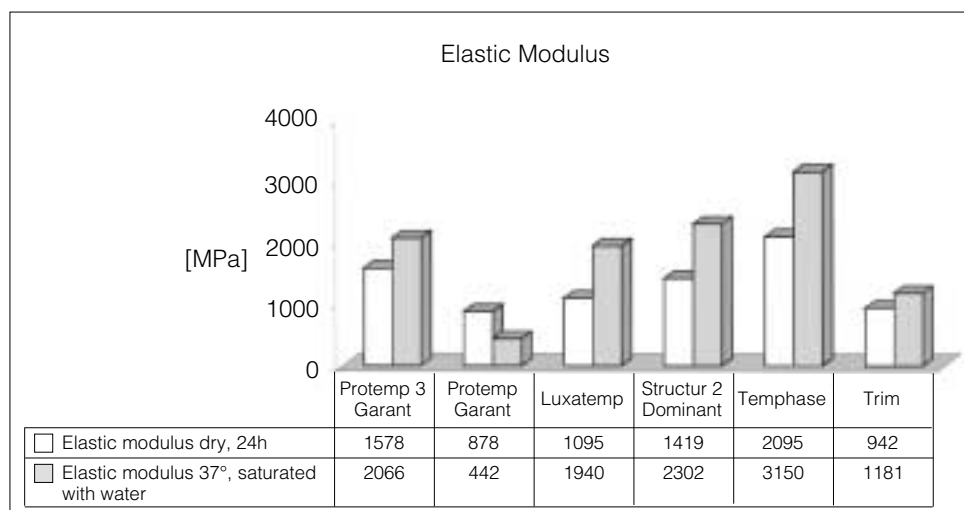


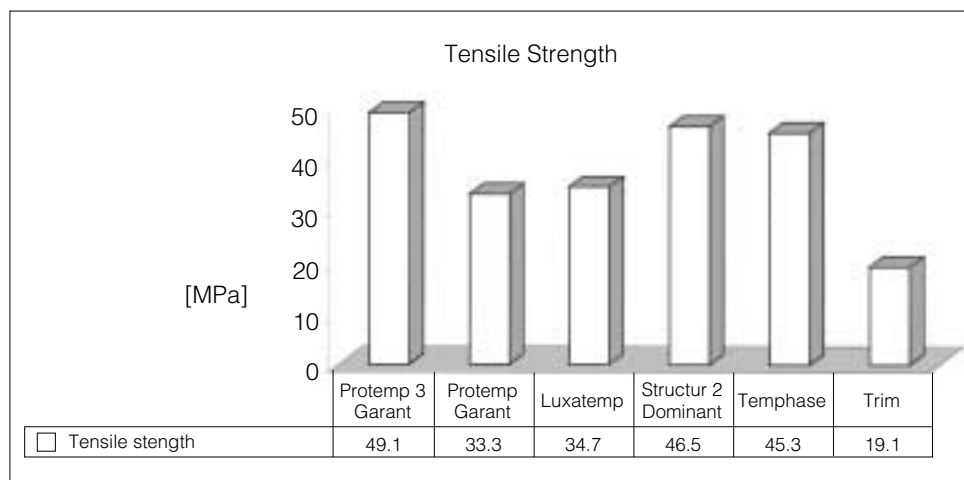
Figure 15.
Elastic modulus as measured
in the 3-point bending test



Flexural strength indicates under which load the test specimen breaks. Deflection shows which distance is tolerated before fracture occurs. As the objective is to avoid fracture where possible, high deflection seems desirable. However, high deflection represents trauma for the periodontium. Limited deflection combined with high flexural strength and a high elastic modulus, as observed for 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material offers the right balance for a high-quality interim restoration.

Information of a similar kind is also provided by the tensile test whose results are shown in Figure 16.

Figure 16.
Tensile test as per DIN 53455



Precision Fit

PD Dr. C.-P. Ernst, I. Harre, Prof. B. Willershausen, University of Mainz

One of the main functions of the temporary restoration is to protect the prepared tooth from thermal, mechanical and chemical influences. High marginal integrity is correspondingly important.

Evaluation of the marginal integrity for a range of temporary crown and bridge materials was the subject of a study performed by the University of Mainz. A new test was developed especially for this purpose.

A standard tooth was prepared for a crown and colored white up to the preparation margin. Temporary crowns were created and applied to the tooth. Marginal inaccuracies were then quantified using digital image analysis of the exposed dentine surfaces (see Figure 17 and Figure 18).

Figure 17.
Digital image analysis

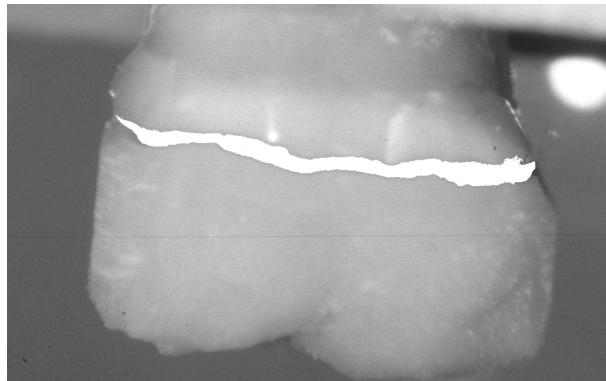
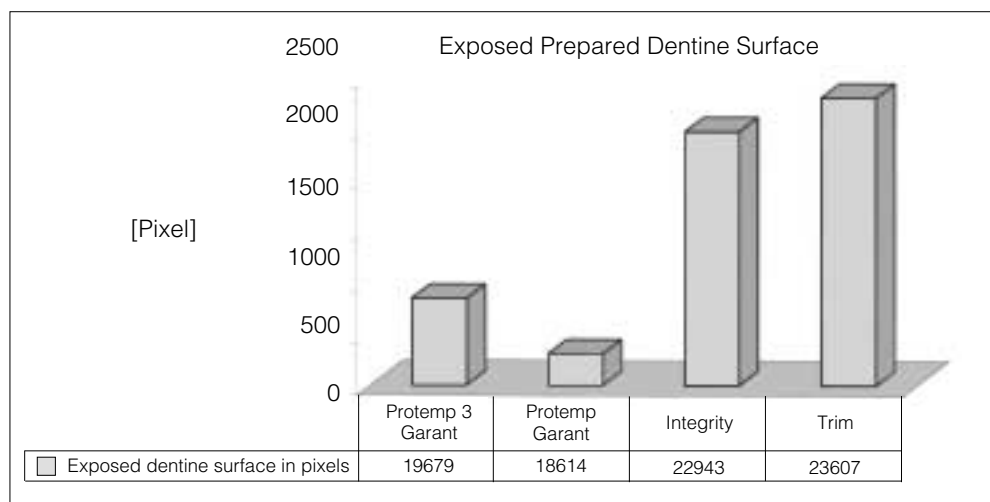


Figure 18.
Quantitative image analysis
of exposed dentine in pixels



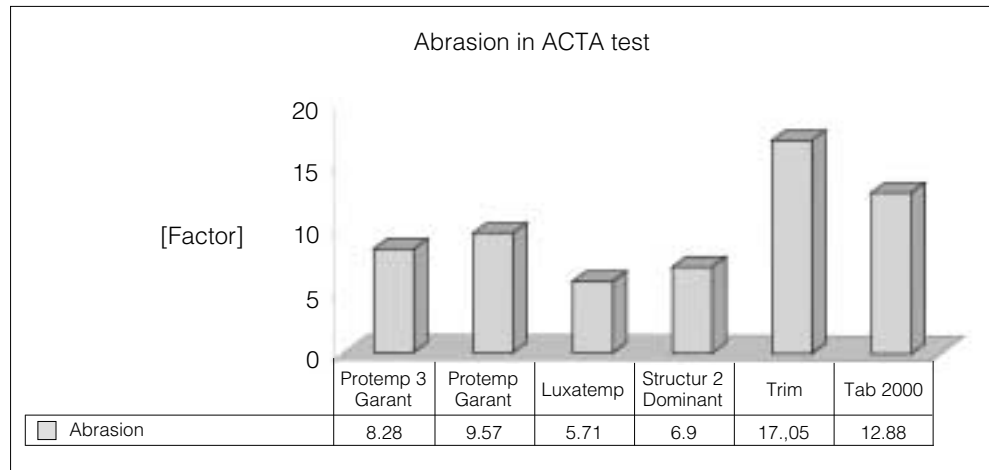
The marginal adaptation of 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material and its predecessor product 3M™ ESPE™ Protemp™ Garant™ Temporization Material is significantly better than that offered by Integrity and Trim.

Abrasion

Prof. D. Welker, Dr. G. Rzanny, Dr. R. Göbel, University of Jena

For the success of the subsequent final prosthetic restoration it is essential for the prepared teeth to not only be protected from irritation but also to maintain or re-establish their position in relation to adjacent teeth and antagonists. The stability of occlusion can be evaluated by determining the wear resistance. Fig. 19 shows the results of the study performed at the University of Jena according to ACTA.

Figure 19.
Wear in ACTA test;
reference material:
non-gamma 2-amalgam
= factor 1



As regards wear resistance, the surface analysis of the abrasion profiles shows that the composite materials are superior to the higher acrylicates as well as to PMMA.

Biocompatibility

A high level of biocompatibility is an essential requirement for every dental material. Where temporary crown and bridge materials are concerned, the focus of attention must fall on the generation of heat during setting and monomer release.

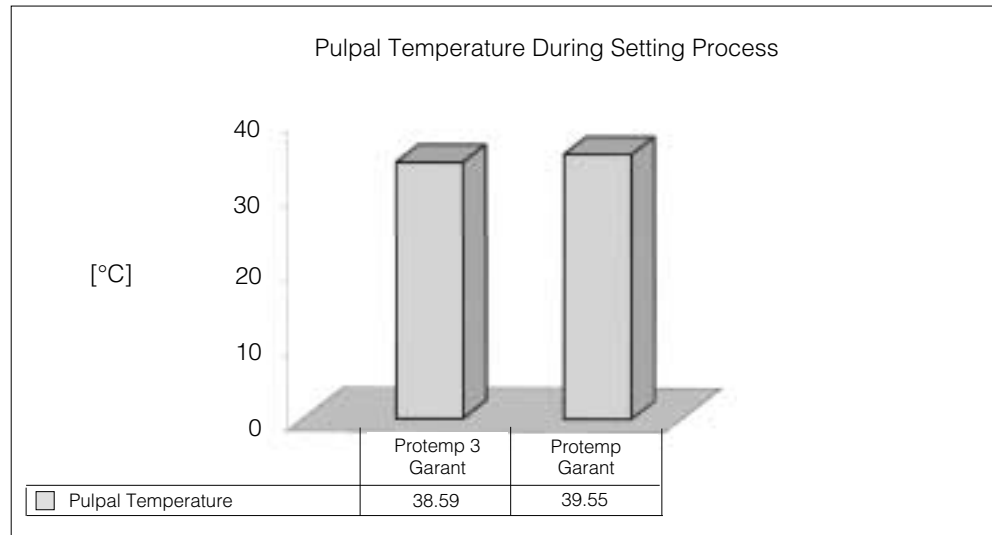
Generation of Heat

Prof. D. Welker, Dr. G. Rzanny, Dr. R. Göbel, University of Jena
Prof. H.-Ch. Lauer, Dr. P. Ottl, Dr. L. Hahn, University of Frankfurt

We basically distinguish between two measurement methods when determining the generation of heat during the setting of materials for temporary crowns and bridges: firstly, internal measurement of the temperature in the pulp cavity of extracted teeth. Here the aim is to take the situation in the mouth into account by simulating it as closely as possible. Secondly, there is the alternative of measuring the temperature directly in the bulk material as it is setting. In this setting, the temperature peaks observed are naturally much greater, and the maximum temperature found varies with the volume of the test specimen. Although temperatures measured in the test specimens cannot be directly related to the clinical situation, they represent a simple method based on material characteristics suitable for the comparison of different products.

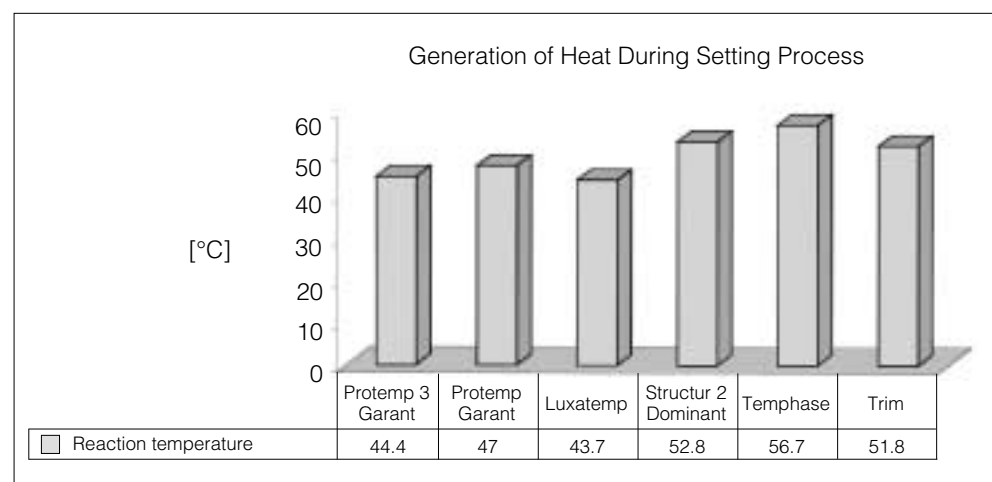
A study performed at the University of Frankfurt under the direction of Professor Lauer measured the average temperature in the pulp chamber during the setting of 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material compared to 3M™ ESPE™ Protemp™ Garant™ Temporization Material. Crown preparations were prepared on extracted teeth. Temporary crown restorations were fabricated over the prepared teeth and the pulpal temperature was measured. The test results are shown in Figure 20. The results show that the average temperature measured in the pulp for Protemp 3 Garant temporization material was only 38.59° C, which is a 1° C reduction in average temperature increase compared to the Protemp Garant temporization material.

Figure 20.
Maximum pulpal temperature measured during exothermal setting



Another study performed by the University of Jena came up with similar results (see Figure 21). A 1 cm³ temperature-insulated sleeve was used to measure the maximum reaction temperature of various crown and bridge materials.

Figure 21.
Generation of heat in 1 cm³ test specimen



The two bisacrylate resins Temphase and Structur 2 SC and the acrylate Trim not only showed a fast setting reaction, but also maximum reaction temperatures which may be unfavorable depending on the clinical situation. Test design used here is 50°C.

With the help of a new, optimized initiator system, it was possible to bring about a improvement in 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material in comparison with 3M™ ESPE™ Protemp™ Garant™ Temporization Material and other manufacturers products with respect to maximum generation of heat.

Monomer Release

3M ESPE internal studies

An internal study carried out by 3M ESPE into residual monomer release in temporary dental crown and bridge resins came to the conclusion that monofunctional acrylates show high residual monomer concentrations (MMA). Protemp 3 Garant temporization material also stands out favorably from standard composite materials in this regard. Monofunctional (meth)acrylates such as HEMA, for example, could not be detected with Protemp 3 Garant temporization material, either. This project will be presented at the annual congress of the DGZPW 2001 in Bad Homburg and published.

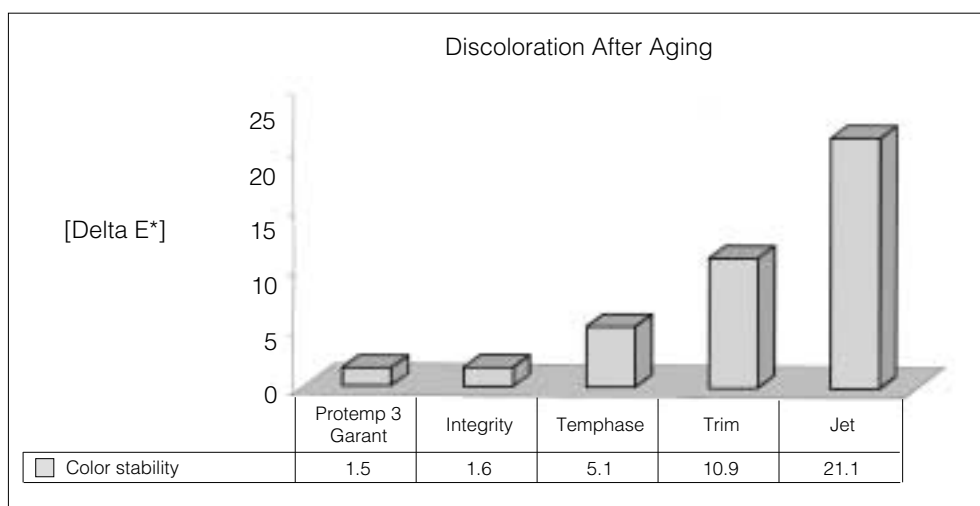
Aesthetics

Prof. Powers, Dr. D. Li, University of Houston
 Dr. A. Fard, Dr. A.L. Neme, Dr. F.E. Pink, University of Detroit Mercy
 3M ESPE internal studies

In the past, the functional aspects of interim restorations predominated, while today's materials also have to cater to the increased demands placed on aesthetics. The patient expects a colorfast restoration while the dentist also attaches importance to the surface finish and good polishability.

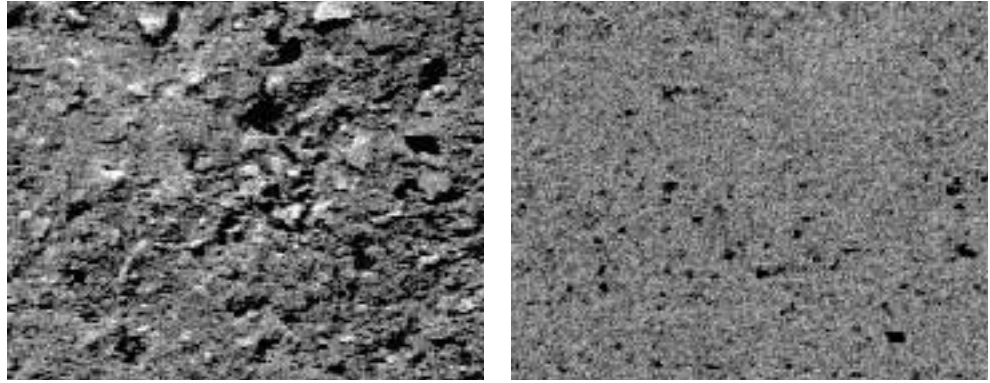
At the University of Houston, color stability was examined using the xenon test after artificial aging with energy irradiation of 45kJ/m². The overall color change (ΔE^*) was determined for each material. The figure included below clearly shows that it was the composite materials Protemp 3 Garant temporization material and Integrity which experienced the smallest changes in color. The monofunctional acrylate Trim and the MMA/PMMA material Jet showed much poorer results.

Figure 22.
 Discoloration after aging in Delta E*



The positive effect on the surface finish produced by the new filler technology used for 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material is impressively demonstrated by two SEM pictures (Figure 23). On the left we can see the surface of 3M™ ESPE™ Protemp™ Garant™ Temporization Material, and on the right that of Protemp 3 Garant temporization material. Anterior bridges were produced using both materials with the help of a silicone impression and left unpolished.

Figure 23.
SEM pictures of unpolished test specimens, 500 fold

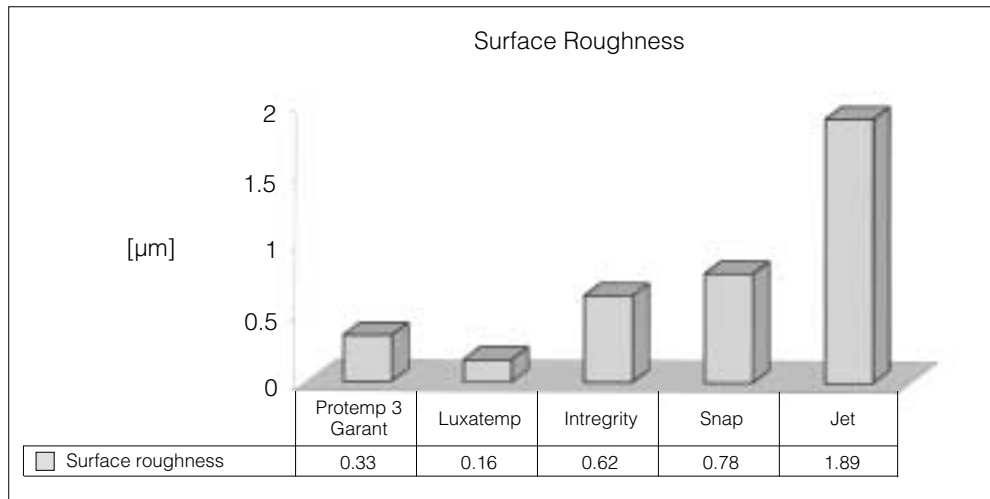


Prottemp Garant Temporization Material

Prottemp 3 Garant Temporization Material

This situation is also clearly reflected in a study into polishing. This study compared two surface finishing techniques and evaluated them by means of profilometric scanning. The study performed at the University of Detroit Mercy showed low surface roughness prior to polishing for Prottemp 3 Garant temporization material and Luxatemp. In all cases, finishing with a diamond finishing bur resulted in smoother surfaces than with the use of discs, while the use of pumice tended to have an adverse effect.

Figure 24.
Comparison of surface roughness



Individualization

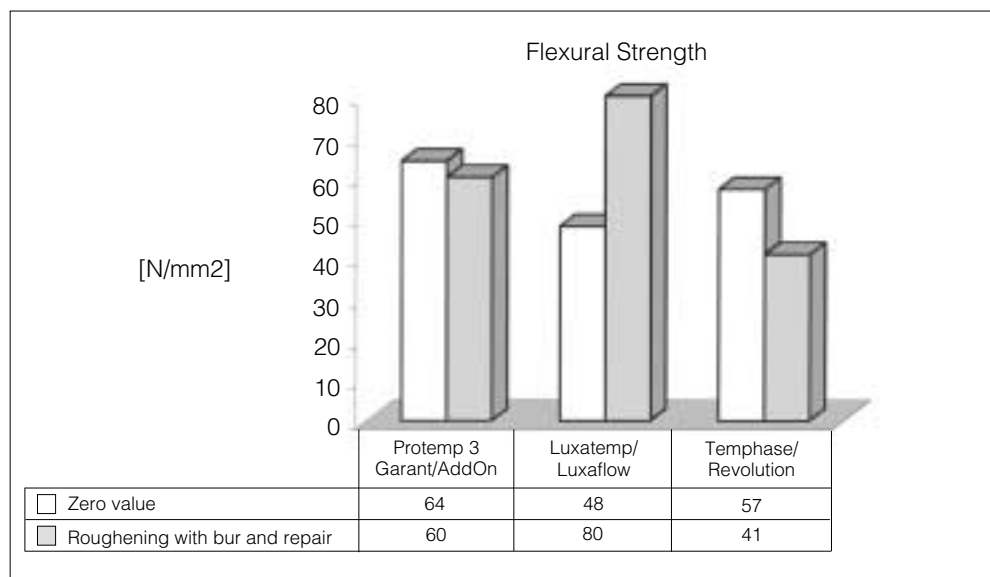
M. Rosentritt, Dr. M. Behr, Dr. R. Lang, Prof. G. Handel, University of Regensburg

Despite the uncontested disadvantages of MMA/PMMA materials and higher acrylates, they are still used at the dental practice due to the easier manipulation of colors and supplementation, repair of minor voids etc. One of the objectives for the development of 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material was to allow for the individualization of color and form using a simple and high-quality technique. For this purpose, Protemp 3 Garant temporization material was ideally adapted to the flowable composite, 3M™ ESPE™ Protemp™ 3 AddOn Material. In particular, the aim was to ensure retention of Protemp 3 Garant temporization material's tough-elastic characteristics even after supplementation. The dentist now has at his disposal a flowable, light-curable composite available in a wide range of colors. Another handling benefit is the fact that, both in the freshly made state and after aging (after wearing by the patient), the temporary restoration only has to be roughened. Additional bonding is not required.

If desired, supplementation or repair can also be carried out using other flowable composites according to the manufacturer's instructions. The use of Protemp 3 Garant temporization material as a self-curing supplementation composite is also possible.

The high performance offered by Protemp 3 AddOn as an add-on material for Protemp 3 Garant temporization material was confirmed by data from a scientific study conducted at the University of Regensburg (see Figure 25). Protemp 3 Garant temporization material test specimens offered identical levels of flexural strength before and after repair with Protemp 3 AddOn material. Luxatemp showed lower initial values. Although they exhibited higher flexural strengths after repair in some cases, they became brittle due to the repair composite. This is shown – as previously described – in a marked reduction in deflection values before fracture.

Figure 25.
Flexural strength after immersion of test specimen in water (7 and 14 days) and roughening of test specimens using a bur

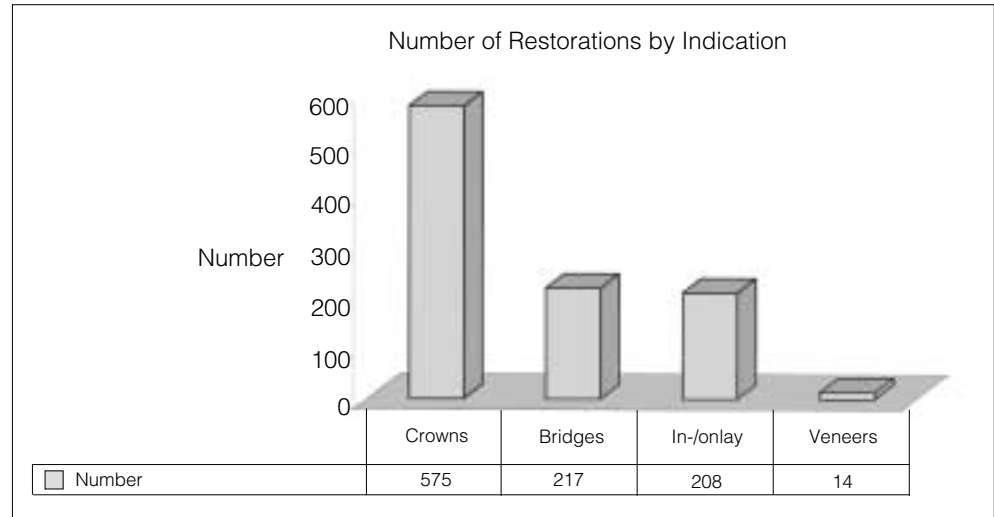


3M ESPE Internal Application Test

In an application test, 36 dentists carried out a total of 1,014 temporary restorations using 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material. The observation period was 9 weeks. The dentists used a questionnaire to report their experiences with use and application of the product.

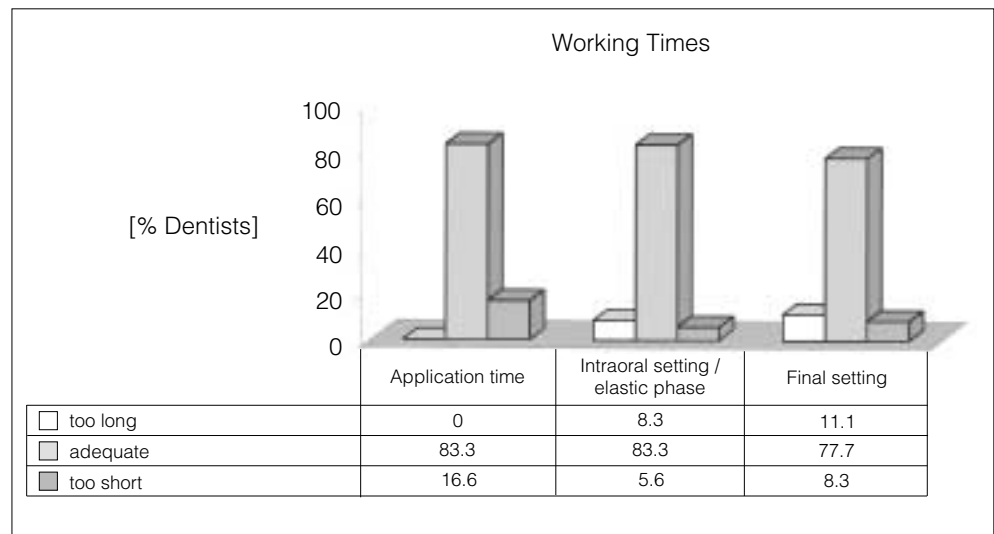
In terms of indications, crowns accounted for 56.7% of the restorations, bridges for 21.4%, inlays/onlays for 20.5% and veneers for 1.4% (see Figure 26).

Figure 26.
Number of temporary restorations carried out according to indication



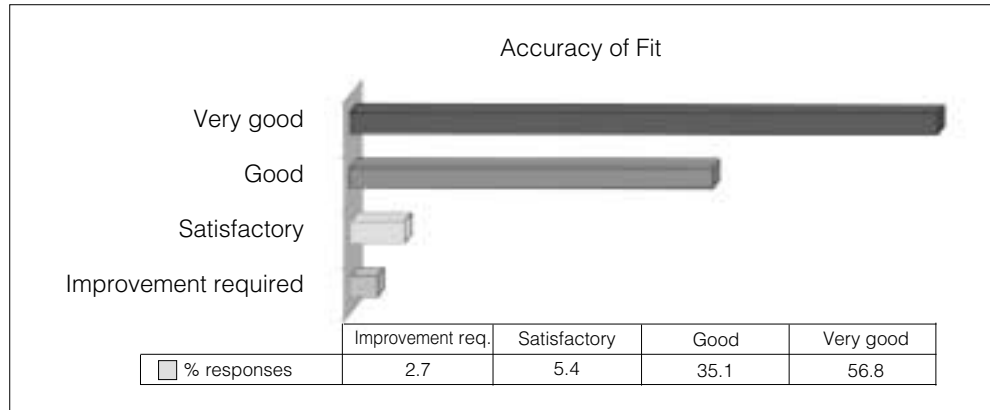
The working times were rated as good in all cases. The study asked about the key times for the work steps: application time, curing in the mouth/elastic phase and final curing/setting time (see Figure 27).

Figure 27.
Assessment of working times



The accuracy of the fit for the interim restorations produced was rated as flawless both on the preparation and as regards occlusal contacts (Figure 28).

Figure 28.
Assessment of accuracy of fit



A good overall rating was given for finishing. The individual results are shown in the following table.

Table 3.
Assessment of finishing;
% replies

	Very good	Good	Satisfactory	Improvement req.
Ease of grinding	41.6	41.6	13.9	2.9
Finishing of fine margins	33.3	52.8	13.9	0
Polishability	33.3	55.6	11.1	0
Ease of finishing overall	30.6	58.3	11.1	0

The in-vitro studies described in the previous section indicated 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material to be a highly stable material with little risk of fracture. However, a material's true clinical qualities can ultimately only be proven by in vivo tests. This application test resulted in a fracture rate of only 1.3%, corresponding to just 13 restorations out of the 1,014 placed for a 98.7% success rate. Their numbers by indication were as follows:

- Two partial crowns
- Three inlays
- Four five-unit, two four-unit and one three-unit bridge

74.3% of the dentists stated that they had not observed a single fracture.

Summary

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material is a temporary crown and bridge material used with the direct technique for:

- crowns
- bridges
- inlays
- onlays
- veneers
- lining of prefabricated crowns

Protemp 3 Garant temporization material represents an innovative improvement of composite-based temporary crown and bridge materials.

Protemp 3 Garant temporization material is thus following the trend towards ever simpler yet higher-quality direct temporary restoration materials. When used in combination with the new 3M™ ESPE™ Garant™ 2 Dispensing System, handling also becomes less complicated and more reliable.

The new monomer system developed by 3M ESPE offers outstanding mechanical strength and high resistance to fracture without the brittleness associated with composites. High flexural strength combined with reversible deflection is achieved by cushioning short-term peak forces without resulting in fracture or splintering of the restoration. The clinical consequence is an extremely stable interim restoration, including bridges with wide spans.

Protemp 3 Garant temporization material is characterized by its precision fit. The restorations produced do not require laborious reworking and offer the preparation, the gingiva and the periodontium ideal protection. The clinical result is assured by an excellent marginal seal and stable occlusion as well as proximal support. The prerequisite for this is an elastic phase which has been optimized in terms of time and material characteristics and ensures reliable removal of the temporary restoration without permitting distortion, fractures or dimensional changes.

A further reduction in the generation of heat during setting provides Protemp 3 Garant temporization material with high biocompatibility. Unlike monofunctional acrylates, which show high residual monomer concentrations (MMA), no release of monofunctional (meth)acrylates such as HEMA could be detected for Protemp 3 Garant temporization material. In this regard, Protemp 3 Garant temporization material distinguishes itself from standard composite materials in a positive way.

The product offers a smooth surface thanks to new filler technology and an optimized initiator system. The greatly reduced inhibition layer contributes to simple and fast polishing with reduced dust levels.

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material satisfies patient requirements for aesthetically appealing temporary restorations. The 4 shades, A1 (extra-bright), A3 (bright), B3 (yellow) and B0.5 (bleach) based on the Vita™ system of shades, provide for comprehensive treatment of all clinical cases.

If required, individualization or adjustments in shape are absolutely simple to perform. Supplementation of Protemp 3 Garant temporization material is possible without additional bonding using both Protemp 3 Garant temporization material and the flowable composite 3M™ ESPE™ Protemp™ 3 AddOn Material. This can be done on the freshly-made or on the worn temporary restoration.

The new 3M™ ESPE™ Garant™ 2 Dispenser System has further benefits to offer. For example, Protemp 3 Garant temporization material can be dispensed easily from the 10:1 cartridge. In addition, more material can be applied to the temporary restoration matrix in less time. This is user-friendly and reliable. A uniform and reproducible setting time is the direct result for everyday applications in the dental operator. This reliability aspect of plugging prevention has been achieved by incorporating separate cartridge openings for the base and catalyst paste which prevents cross-contamination of the pastes.

Innovative developments for the initiator, matrix and filler as well as a new cartridge system make Protemp 3 Garant temporization material a next-generation temporary crown and bridge material. Clinical aspects and handling characteristics have been optimized likewise, ensuring that daily application in the dental operator is easy and convenient.

Instructions for Use

3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material

Device Description

Product Description

Protemp™ 3 Garant™ Temporization Material manufactured by 3M ESPE is a composite material for the fabrication of temporary restoration at the chairside. Based on multi-functional methacrylate esters, this two-component system has restorative material-like properties and is available in several shades: A1, A3, bleach shade B0.5 and B3. With the 3M™ ESPE™ Garant™ 2 Dispenser manufactured for 3M ESPE the material can be applied directly from the cartridge without causing voids.

Temporary restorations manufactured with Protemp 3 Garant temporization material can be built-up and individualized with 3M™ ESPE™ Protemp™ 3 AddOn composite A1, A3, B0.5 and B3 manufactured by 3M ESPE. Protemp 3 Garant temporization material and flowable composites can also be used.

For details on the products, Garant 2 Dispenser and Procem™ manufactured by 3M ESPE please refer to the corresponding Instructions for Use.

Instructions for Use should not be discarded for the duration of product use.

Application Areas

- Fabrication of temporary crowns, bridges, inlays, onlays and veneers.
- Crown lining material for 3M™ ESPE™ Prefabricated Temporary Crowns.

Dispensing and Mixing

The pastes are dispensed and auto-mixed from the Garant 2 dispenser. Allow refrigerated material to equilibrate to room temperature (73°F) before use. Use the enclosed blue Garant 2 Mixing tips only!

Operational check for new cartridges:

- Remove and discard the cartridge cap.
- Check whether both cartridge openings are free from obstruction and remove obstructing material, if any, with a suitable instrument.
- Extrude a small quantity of base paste and catalyst each until both pastes emerge uniformly.

Times

At room temperature (73°F) and 50% relative humidity the following time periods are available for processing:

min : sec				
00:00	00 :50	01 :35	02 :30	05 :00
Fill the impression and reposition in the mouth	Setting in the mouth	Withdrawal from the mouth	Complete setting	Finishing

Storage and Stability

Do not store the product above 77°F.

Do not use after the expiration date.

Device Preparation

Preparatory Work

- Take an alginate or silicone impression from the intact row of teeth.
- Instead of an impression, a laboratory-made vacuum-formed template or, for single crowns, a preformed crown can be used for shaping.
- To enhance the strength of the temporary restoration, remove interproximal grooves in the impression. If required due to tight spacing conditions, enlarge the relevant sites by cutting.
- For easy replacement in the mouth, relieve undercuts.
- With missing teeth or gaps in the molar area, cut a groove in the impression to produce a stable, bar-shaped connection in the temporary restoration.
- If required, prior to taking the impression close any gaps between front teeth with denture teeth acting as spacers; interlock multiple denture teeth with wax.

Application

Use gentle and consistent pressure to dispense material from the mixing tip. Increasing the pressure does not accelerate the flow! The flow of material is interrupted as soon as the pressure on the handle is reduced. Material that has set inside the mixing tip should not be extruded by force, as this may damage both the cartridge and the mixing tip.

- First, install a new mixing tip.
- Prior to each application, extrude a small amount (pea-sized) material from the mixing tip onto a mixing pad and discard this material.
- Subsequently, load the dried impression or vacuum-formed template in the relevant spaces from bottom up.
- Reposition the impression or vacuum-formed template in the mouth.
- The material attains a hard-elastic consistency approximately 1 min 35 sec after the onset of mixing. The material and the impression or vacuum-formed template must be removed from the mouth within approximately 2 min 30 sec after the onset of mixing.
- Store cartridge with used mixing tip attached until next use.

Finishing

Do not breathe polishing dust; use suitable mouth protective device or aspiration!

- Finish the temporary restoration once the material is completely cured (not earlier than 5 minutes after the onset of mixing) using fine carbide burs. Polish if desired.
 - Remove oxygen-inhibited layer on the surface of the restoration with organic solvents such as ethanol.

Individualization/Shape Correction

Using 3M™ ESPE™ Protemp™ 3 AddOn Material and 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material for custom-shaping and shape correction there usually is no need for a bonding agent. If you intend to use other products, please refer to the pertinent manufacturer's Instructions for Use.

Compatible Products

- Protemp 3 AddOn composites
- Flowable composites. Please comply with the corresponding Instructions for Use!
- Protemp 3 Garant temporization material

Application of Protemp 3 Garant Temporization Material

- Processing: please refer to the information provided under “Application” and “Finishing.”

Application of Protemp 3 AddOn to New Temporary Restorations

In newly manufactured temporary restorations, Protemp 3 AddOn material can be applied either to the finished surface or the unprocessed, but clean, oxygen inhibition layer. Bonding is excellent in either case.

- Any contamination - e. g. from saliva or polishing dust - should be removed with alcohol from temporary restorations with inhibition layers and finished temporary restorations, which should then be dried with a stream of air.
Alternatively:
If the inhibition layer or the finished restoration is clean, proceed as described in the next step.
- For reasons of hygiene, dispense Protemp 3 AddOn composite onto a mixing pad.
- Apply the composite in 1 mm increments to the temporary restoration.
- Light-cure each increment for 5 seconds.
- Finish and polish the restoration with carbide burs and polish with polishing paste.

Application of Flowable Composites to New Temporary Restorations

- Remove the oxygen-inhibited layer from the restoration.
- Thoroughly roughen the surface of the temporary restoration with rotary instruments.
- Remove any contamination - e. g. from saliva or polishing dust - with alcohol, then dry the restoration with a stream of air.
- Place flowable composite following the manufacturer's instructions.

Application of Protemp 3 AddOn Material to Temporary Restorations that were in Use

- Thoroughly roughen the surface of the temporary restoration with rotary instruments.
- Remove any contamination e. g. from saliva or polishing dust - with alcohol, then dry the restoration with a stream of air.

-
- For reasons of hygiene, dispense 3M™ ESPE™ Protemp™ 3 AddOn composite onto a mixing pad.
 - Apply the composite in 1 mm increments to the temporary restoration.
 - Light-cure each increment for 5 seconds.
 - Finish and polish the restoration with carbide burs and polish with polishing paste.

Application of Flowable Composites to Temporary Restorations that were in Use

- Thoroughly roughen the surface of the temporary restoration with rotary instruments.
- Remove any contamination - e. g. from saliva or polishing dust - with alcohol, then dry the restoration with a stream of air.
- Place flowable composite following the manufacturer's instructions.

Technique for Lining Prefabricated Temporary Crowns

- Trim, contour and crimp temporary crown to fit crown preparation.
- When a satisfactory fit has been achieved, dispense the 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material into the prefabricated crown. Fill the crown slightly over half with material. Do not overfill.

Note: When using a polycarbonate crown, it is recommended that a thin layer of methylmethacrylate be brushed on the inner surface of the crown and air dried for better adhesion.

- Seat crown into place and guide patient into occlusion for posterior crowns.
- Remove crown from prepared tooth 1: 35 min: sec after dispensing. If desired, it may remain in the mouth for as long as 5 minutes.
- Trim excess material at the margins.
- Reseat crown on the tooth preparation to verify proper fit.
- Cement crown with a temporary cement. Refer to the information provided under "cementation."

Cementation

Eugenol-containing temporary cements may impair the setting or bonding of the permanent cement when seating the final restoration.

- Insert the temporary restoration with a commercial temporary cement, e. g. 3M™ ESPE™ Procem™ Temporary Cement.

Cementation of Veneers

For improved esthetics, the Protemp 3 Garant temporary veneers can be temporarily cemented using the "bonded button technique" with a permanent resin cement.

- Spot etch the center of the facial surface approximately 1-2 mm for 20 seconds with standard phosphoric acid etching gel.

Caution: Etching beyond the 1-2 mm area will cause difficulty in removal of the temporary veneer.

- Blot excess water leaving the tooth moist.

-
- Seat the temporary veneer with a resin cement, e. g. 3M™ ESPE™ RelyX™ Veneer Cement or 3M™ ESPE™ Compolute™, both manufactured by 3M ESPE, making sure that the composite is not bonded to the entire surface, otherwise removal will be impeded.
 - Lightcure and clean up the resin cement according to the manufacturer's recommendations.

Removing the Temporary Restoration

- Remove the restoration using an appropriate instrument.
- Remove residual cement.
- Bond the final restoration in the usual manner.

Repair

- If a restoration breaks shortly after fabrication, repair it using a fresh mix of 3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material.
- Breakage of older or worn restorations: Roughen the fractured surfaces and adjacent areas, place undercuts and re-assemble and bond the pieces in the proper orientation using a fresh mix of Protemp 3 Garant temporization material.
- Once the material is fully set, finish as usual.

Cleaning

Paste that has not set can be removed with organic solvents.

Warnings

Protemp 3 Garant temporization material contains acrylate resins. Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resins. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If cement contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.

Warranty

Protemp 3 Garant temporization material is provided "as is" without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, or non-infringement. 3M ESPE shall not be liable for any special, indirect, incidental, consequential, or punitive damages, including without limitation, lost revenues or lost profits, which may result from the use of, access to, or inability to use these materials. Because some states do not allow the exclusion or limitation of liability for consequential or incidental damages, the above limitation or exclusion may not apply to you. Before using Protemp 3 Garant temporization material, the user should determine the suitability of using Protemp 3 Garant temporization material for the proposed use. The user assumes any and all risks and liability related to the use of Protemp 3 Garant temporization material. 3M ESPE will replace Protemp 3 Garant temporization material that is proved to be defective.

Information valid as of: 06/01

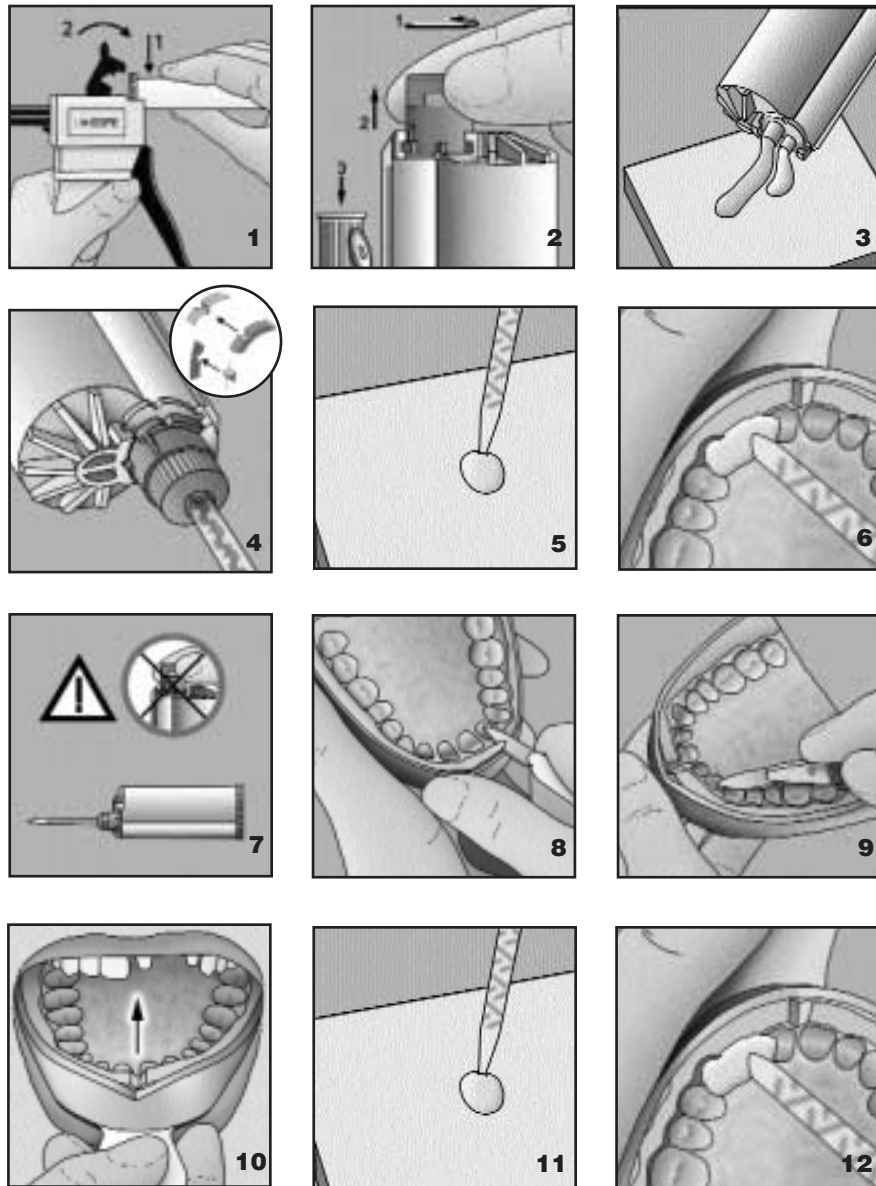
Step-by-Step Card

3M ESPE Protemp™ 3 Garant™ Temporization Material

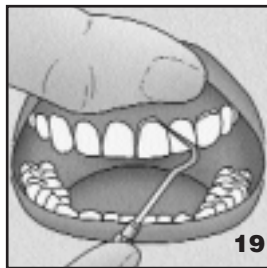
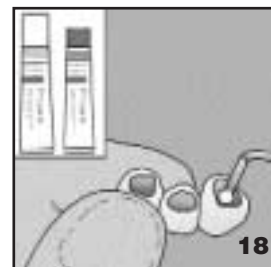
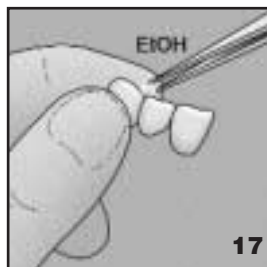
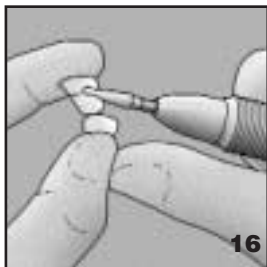
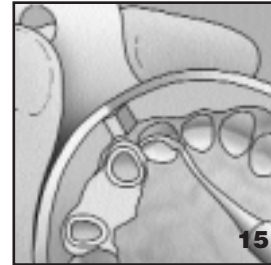
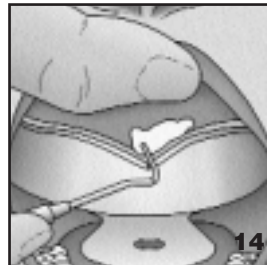
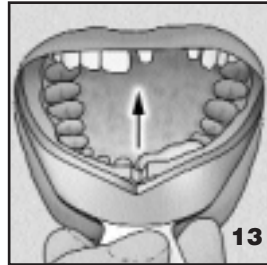
Composite for Temporary Crowns and Bridges

Indications:

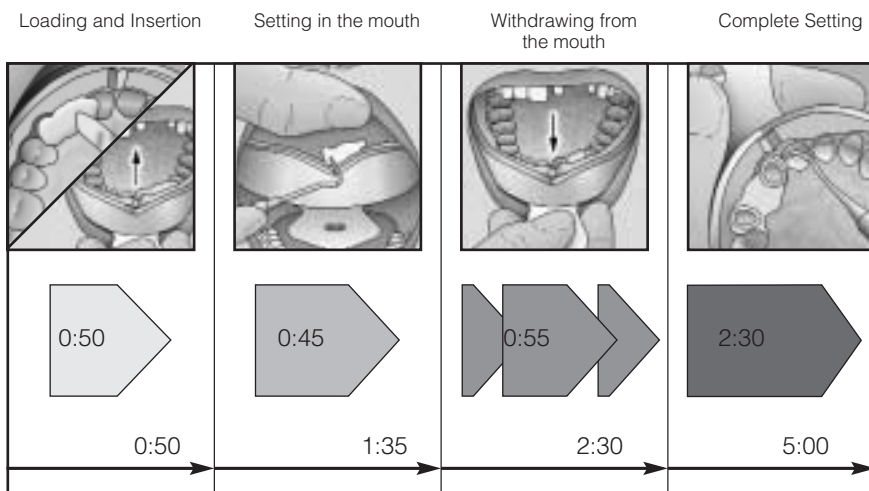
Fabrication of Temporary Crowns, Bridges, Inlays, Onlays, Veneers



3M™ ESPE™ Protemp™ 3 Garant™ Temporization Material
Step by Step Card, *continued*



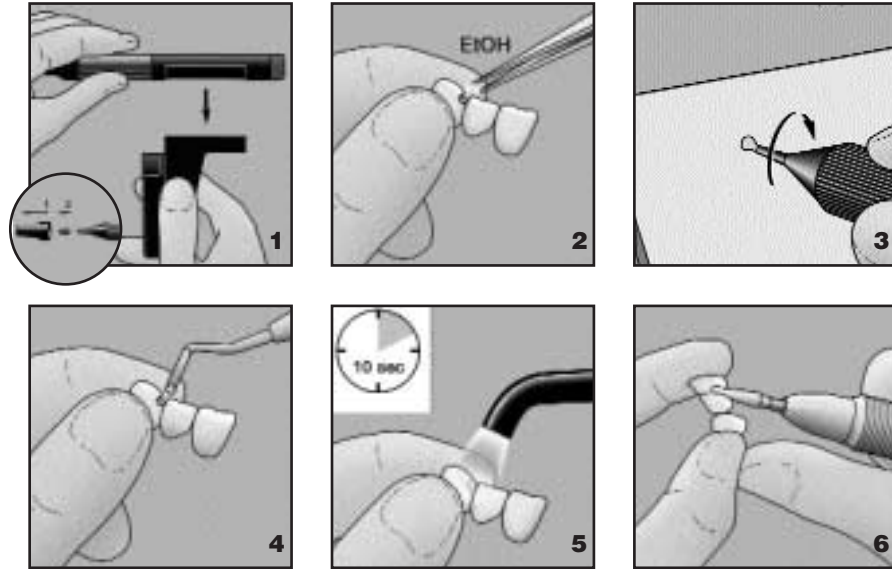
Timetable



3M ESPE

Protemp™ 3 AddOn Material

Composite for Individualization/Shape Correction



3M ESPE

3M ESPE
St. Paul, MN 55144-1000
Toll-free: 1-800-634-2249
<http://www.3MESPE.com/>

Made in Germany

746935/01 (06.01)

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