

3M ESPE

Protemp™ Crown
Temporization Material

technical product profile

Protemp

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Introduction

Temporary crown and bridge restorations are essential interim solutions that stabilize and protect tooth structure during the time span from final impression through the final laboratory-fabricated crown or bridge restoration. “Temporary” and “provisional” are terms that are synonymous in dentistry. The temporary restoration must protect the tooth structure from the rigors of the oral environment and demand high quality materials.

Crown and bridge restorations require several distinct treatment phases for completion. A temporary restoration is needed during the interim phase. Dental professionals must maintain function with a temporary restoration. In addition to stabilize and protect existing tooth structure, materials are expected to be tough (fracture resistant and flexible), retain a natural looking appearance and maintain space and longevity. The rapid evolution of esthetic restorative materials, such as composites and ceramics, has been accompanied by improvements of temporary materials. Currently, a large number of temporary materials are available for the effective restoration of prepared teeth.

Background

Temporary materials are classified in two distinct categories. They are prefabricated crowns and chemical-cured materials.

Prefabricated Crowns

Prefabricated Crowns are available in many forms for a variety of single-unit applications. Since 1975, 3M ESPE has been a market leader in prefabricated crowns. Their use has a broad application base from short-term to longer-term coverage. Prefabricated temporary crowns provide accurate anatomy and the ability to fit while conforming to the margin. The 3M ESPE Iso-Form™, Gold Anodized and Polycarbonate Crowns are easy to place and save time while maintaining tooth function.

Chemical-cured Materials

Powder/Liquid Acrylic

Powder/liquid acrylics have been used for temporary restorations since the late 1930's for both single and multiple-unit temporary restorations. Two types of acrylic materials are sold today.

The oldest group of polymer-based direct temporary materials are the acrylic MMA/PMMA resins. Polymethyl methacrylate microbead powder (PMMA) is mixed with a methyl methacrylate monomer (MMA) liquid (e.g. Jet™, Alike™). The high level of monomer release should not be underestimated, in particular when regarding the application to the freshly prepared tooth using the direct technique. The result is a highly exothermic setting reaction requiring the early removal of the temporary restoration from the preparation to prevent damage to the pulp. This could result in an unsatisfactory fit due to the subsequent polymerization shrinkage.

Materials made of monofunctional acrylate monomers (e.g. Snap™, Trim® II) with a higher molecular weight have been developed to eliminate some of the disadvantages of polymethyl methacrylate systems. These materials also involve a powder/liquid system which is mixed by hand. The materials consist of blends of polyethyl methacrylate powder and a

methacrylate resin (Ethyl, Isobutyl or Vinyl). This results in a lower setting temperature and, in comparison with PMMA materials, slightly enhanced mechanical strengths which are offset by poor esthetics and resistance to chewing forces. In addition, the restorations can be attacked by cements containing eugenol, a potential disadvantage.

Composite-Based Resin

There are a number of products used for temporary restorations that fall into the general category of composite-based resin systems. Composite-based temporization materials contain two main components, a resin and a filler system.

The resin system is the organic matrix in which other components are dispersed or dissolved. It consists of monomers and can be polymerized.

The filler system consists of discrete particles that are dispersed in the resin system. Size range of the fillers can vary from fine particles (0.5 to 3 μm) to microfine particles (0.04 to 0.2 μm), while shapes can be regular or irregular. Particles of different sizes and shapes are sometimes blended to obtain desired properties. Filler particles are usually surface treated. (See Figure 1 - not drawn to scale).

Figure 1. Composite – Based Resin and Filler System

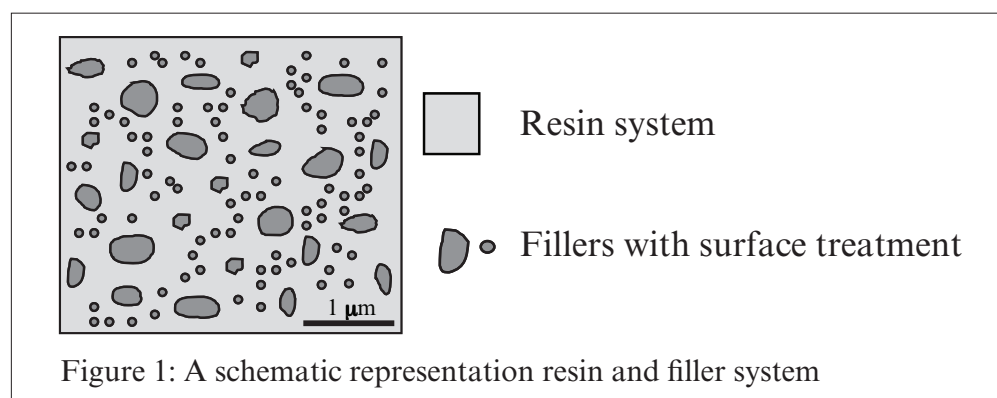


Figure 1: A schematic representation resin and filler system

The most common, and successful class of material on the market is the group of Bis-acrylic composites (e.g. Protemp™ 3 Garant™, Luxatemp®, Integrity™, Structur® Premium). Comparable with composites used for direct restorations, these materials consist of an organic resin system 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 as the organic resin system. The inorganic fillers account for approximately 40% by weight in the bis-acrylic paste formulations. The introduction of the bis-acrylic systems for temporary restorations provides a material 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 auto-mix cartridge systems in the early 90s, it also became possible to satisfy the demands for simple, clean and fast handling.

Protemp™ 3 Garant™ Temporization Material

In 2002, 3M ESPE introduced Protemp 3 Garant Temporization Material. Protemp 3 Garant is a strong temporary material with improved resistance to fracture and therefore very low fracture rate. 3M ESPE produced a material that offers superior mechanical properties, reduced polymerization heat, precise fit, and esthetic results. Protemp 3 Garant Temporization Material is one of the toughest composite-based temporary materials on the market today.

Protemp 3 Garant is ideally used for esthetic single and multi-unit restorations including anterior and posterior teeth, veneers, inlays and onlays, as well as crown linings.

Protemp™ Crown Temporization Material

Product Description

The most recent innovative product from 3M ESPE and the Protemp™ family of temporary products is 3M™ ESPE™ Protemp™ Crown Temporization Material for single-unit temporization. The Protemp Crown innovation combines the advantages of composite-based chemical-cured temporization (custom fit and esthetics) with the advantages of prefabricated crowns (fast, easy, no matrix and no mess). It is a preformed malleable composite-based crown that can deliver a custom fit for your patients in less than four minutes. This revolutionary new method for single unit temporization is simple to use while resulting in significant fabrication time saving, custom fit and tooth-colored esthetics.

Indications

Protemp Crown is used for single-unit esthetic temporary restorations in the following permanent dentition without the use of a matrix:

- Molar
- Bicuspid (premolar)
- Cuspid (canine)

Features and Benefits

In addition to the favorable characteristics that a composite-based temporization material such as Protemp 3 Garant Temporization Material provides, the innovative new Protemp Crown Temporization Material has some special features.

The most distinct feature is its unique handling property. In its uncured state Protemp Crown handles like wax (or clay) and can be modeled and reshaped easily using a composite instrument. In the wax stage, the crown can easily be adapted to the tooth preparation, margins, and proximal contacts. Additionally, the patient can gently bite down into the Protemp Crown in its uncured state to form the proper occlusal contacts.

This desired rheology is achieved by using a combination of a special crystalline resin system and highly interacting aggregated inorganic fillers. As a result the material is physically crosslinked and has a 3-dimensional, physically crosslinked structure. (See Figure 2 - not drawn to scale).

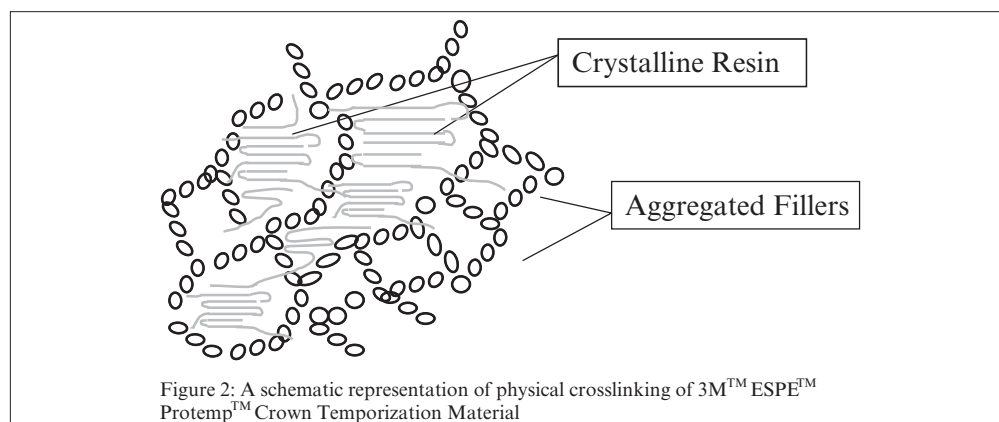


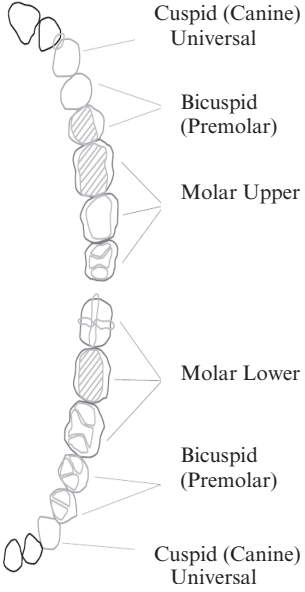
Figure 2. Protemp Crown Resin and Filler Crosslinking

After light-curing, a mechanically stable composite material is obtained that is wear resistant, radiopaque and polishable, due to the highly crosslinked resin and filler systems.

A special feature of Protemp Crown is the delivery method. Unlike all other composite temporary materials that are delivered in a paste/paste or powder/liquid form, Protemp Crown is delivered in the form of an anatomically shaped (preformed) crown. The wax-like malleability of the material in the uncured state makes it possible to use it successfully and quickly on most posterior and canine teeth with nine (9) sizes and shapes. (See Figure 3).

Figure 3. Size and Shape Selection

Size Selection Chart	
Crown Name	Approximate Range Mesial Distal Width
BICUSPID (Premolar) Upper	
Bicuspid (Premolar) Upper S	6 - 7 mm
Bicuspid (Premolar) Upper L	7 - 8 mm
MOLAR (1st & 2nd) Upper	
Molar Upper S	9 - 11 mm
Molar Upper L	11 - 12 mm
CUSPID (Canine) Universal	
Cuspid (Canine) Universal S	6 - 8 mm
Cuspid (Canine) Universal L	8 - 9 mm
BICUSPID (Premolar) Lower	
Bicuspid (Premolar) Lower	6 - 9 mm
MOLARS (1st & 2nd) Lower	
Molar Lower S	9 - 11 mm
Molar Lower L	11 - 12 mm



Another feature of Protemp Crown is the light-activated curing that allows the dental professional to be in control of setting (cure-on-demand). After the customization and fitting steps, a high strength composite temporary crown can be quickly and conveniently obtained simply by light curing using a dental curing light.

Composition

The light-curable resin of Protemp Crown is composed of bis-GMA, and a second functionalized dimethacrylate resin. Silanated zirconia-silica and fumed silica fillers are used to impart physical strength, radiopacity, and wear resistance. The silanated inorganic filler loading is approximately 78% by weight; the average particle size of the filler is approximately 0.6 micrometers. Protemp Crown also contains pigments. The qualitative composition of Protemp Crown Temporization Material is listed in Table below. (See Table 1).

Resin	Filler
Dimethacrylate polymer	Zirconia Silica
bisGMA	Fumed Silica
	Silane
	Pigments

Table 1. Composition

Biocompatibility

Biocompatibility is an essential requirement for dental materials. Protemp Crown and its ingredients were assessed for product safety according to testing guidelines outlined by the FDA (General Program Memorandum G95) and ISO 10993-1: 2003(E) as well as ISO 7405:1997(E). A Diplomate of the American Board of Toxicology found Protemp Crown safe for its intended use.

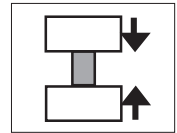
Physical Properties

Protemp Crown is designed to deliver a strong, simple, and fast to customize, single unit temporary crown. This new product combines the advantages of Protemp 3 Garant Temporization Material, like the excellent clinical performance (strength and fracture resistance), custom fit and esthetics, while maintaining the advantages of a prefabricated crown (fast, easy and no matrix or impression). In this section Protemp Crown physical properties are reviewed. Physical property testing was conducted by 3M ESPE unless otherwise noted.

Compressive and Diametral Tensile Strength

Compressive and diametral tensile strength are two common measurements that characterize material strength.

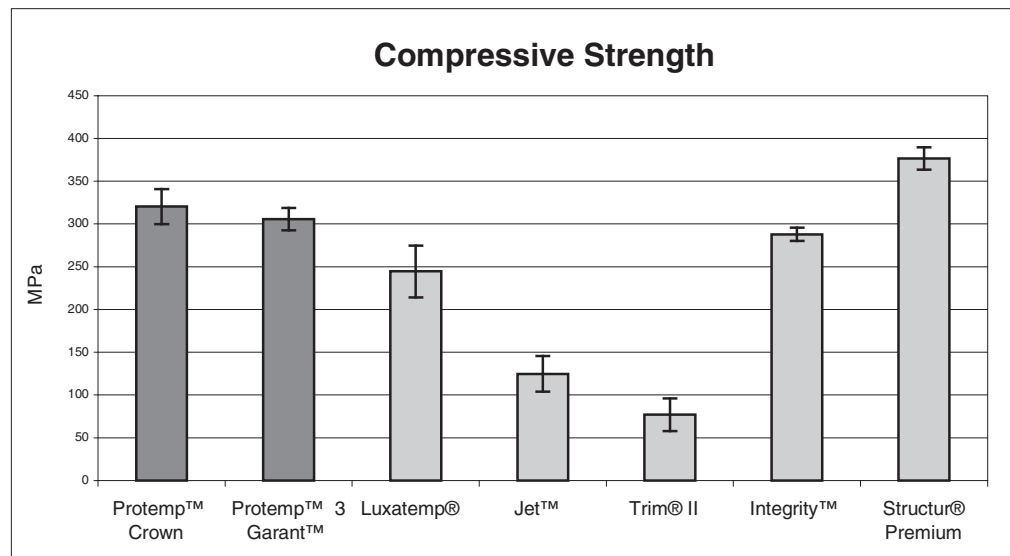
Compressive strength measures the strength of a material when a force is applied. Rods are made of the crown material and simultaneous forces are applied to the opposite ends of the sample length. The sample failure is a result of shear and tensile forces.



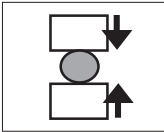
The compressive strength value obtained for Protemp™ Crown Temporization Material is significantly similar to Protemp™ 3 Garant™, Integrity™ and Structur® Premium. However, compressive strength for Protemp Crown was significantly higher than Jet™ and Trim® II and Luxatemp®. A high compressive strength helps to withstand the forces from chewing. The compressive strength of the various materials are shown in Figure 4 below.

(See Figure 4)

Figure 4. Compressive Strength



Diametral tensile strength is measured using a similar test method. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs.



The diametral tensile strength of Protemp™ Crown Temporization Material was significantly higher than Protemp™ 3 Garant™, Luxatemp®, Jet™, and Trim® II. The value for Protemp Crown was statistically similar to Integrity™ and Structur® Premium. The diametral tensile strength values are shown in Figure 5 below. (See Figure 5)

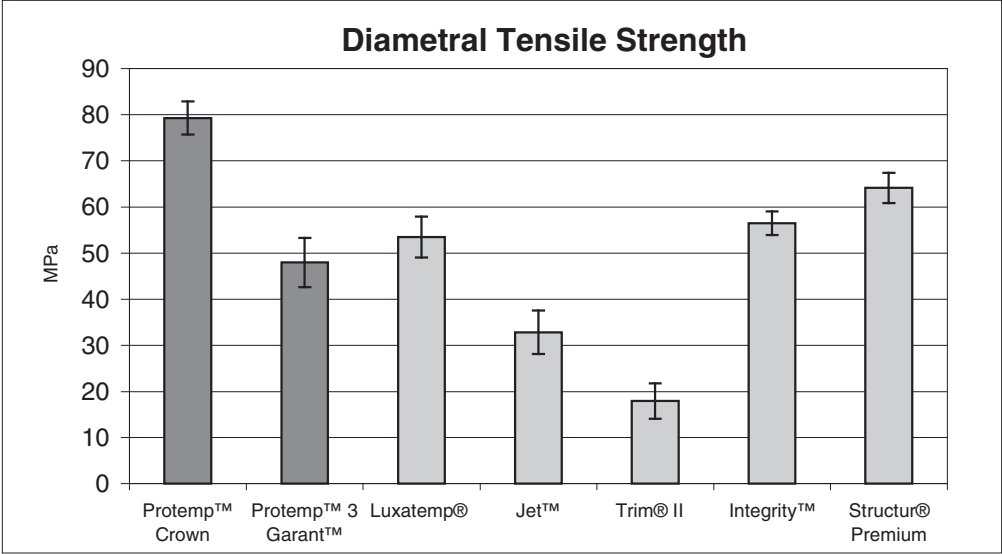
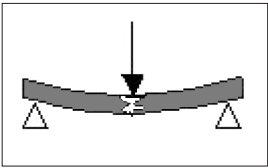


Figure 5. Diametral Tensile Strength

Flexural Strength

Flexural strength is a method of defining a material's strength under bending forces and combines the forces found in compression and tension. This test is conducted by applying a load to a material specimen bar that is supported at each end. Flexural strength is the value obtained when the sample breaks.



A high flexural strength contributes to the durability of a temporary restoration. The flexural strength of Protemp™ Crown Temporization Material was statistically higher than the values of the other materials tested. (See Figure 6).

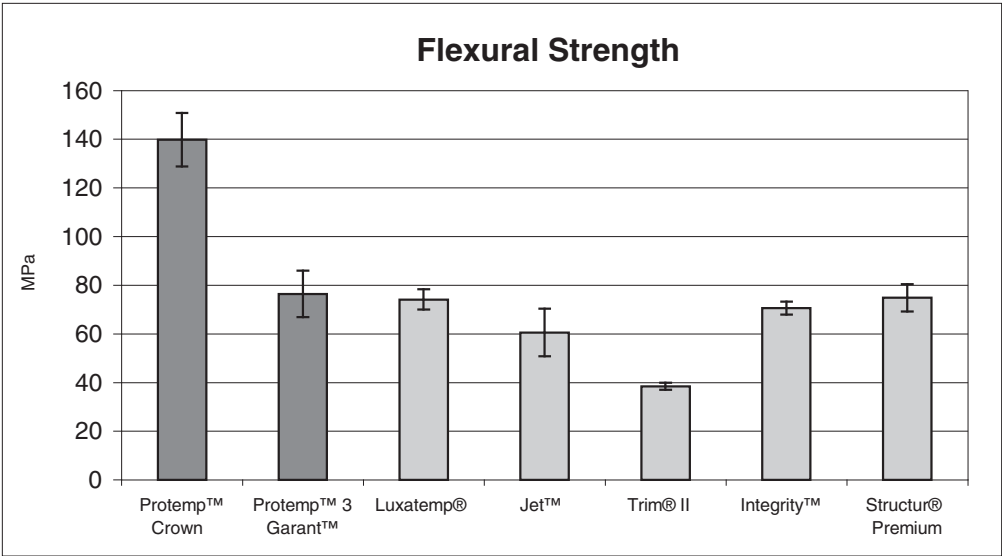
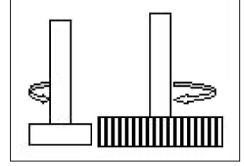


Figure 6. Flexural Strength

Wear Rate

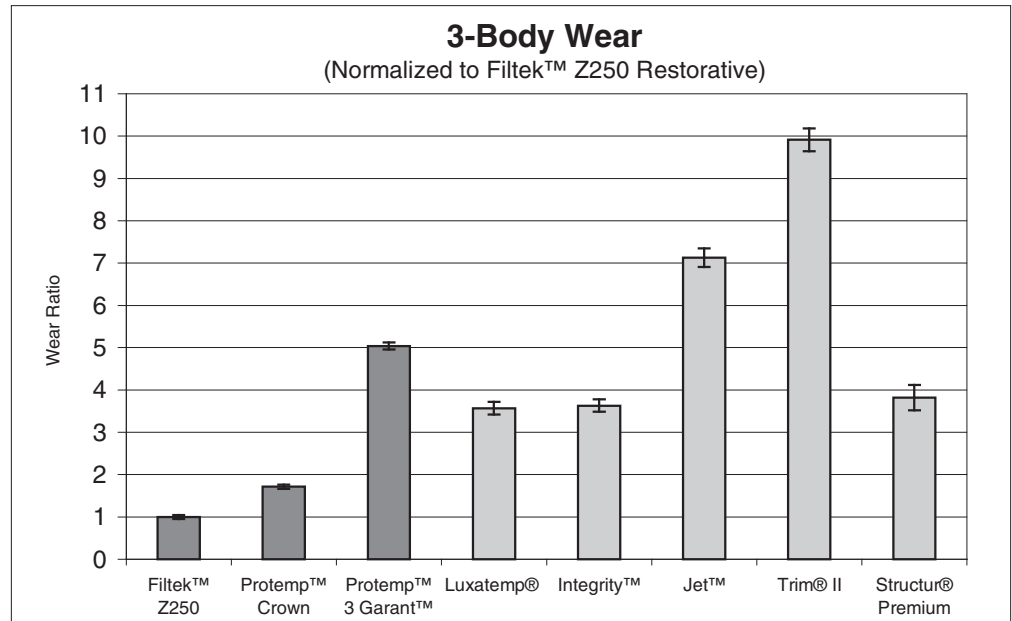
The measurement of wear is critical as an indicator of longevity and space maintenance in temporary restorations. 3M ESPE uses the ACTA (Academic Centre for Dentistry Amsterdam) three-body wear machine and test method for wear rate measurements.

The wear rate is determined by a three-body wear test and compared to other temporization materials and 3M™ ESPE™ Filtek™ Z250 (a restorative material used as a control). In this test, Filtek Z250 Restorative and the temporization materials (1st body) are placed and cured onto a wheel (shaded slots in the diagram); the test wheel then contacts another wheel acting as an “antagonistic cusp” (2nd body). The two wheels counter-rotate against one another, dragging an abrasive slurry (3rd body) between them. Volume loss of the test materials is measured following a predefined cycle of wheel rotations.



The wear rate of Protemp™ Crown Temporization Material was significantly lower than Trim® II and Jet® and showed the least wear rate when compared to Protemp™ 3 Garant™, Luxatemp®, Integrity™ and Structur® Premium. Protemp Crown wear values were close to the control, Filtek™ Z250 Restorative. The wear rate values are shown in Figure 7 below. (See Figure 7)

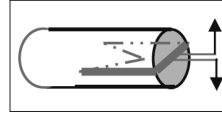
Figure 7. Wear Rate



Fracture Toughness

Delong R, MDRCBB:University of Minnesota, USA

Fracture toughness was determined by an in-vitro short rod fracture toughness test. Fracture toughness (K_{Ic}) is related to the energy required to propagate a crack. In this test a chevron notch is cut into a cured cylinder and the parts on either side of the chevron are pulled apart.



The fracture toughness data shown below indicates that the short rod fracture toughness of Protemp Crown is higher than Luxatemp®, Jet™, and Trim® II, Structur® Premium and equivalent to Protemp™ 3 Garant™ Temporization Material, and two 3M ESPE restorative materials, Z100™ Restorative and Sinfony™ Indirect Lab Composite. (See Figure 8)

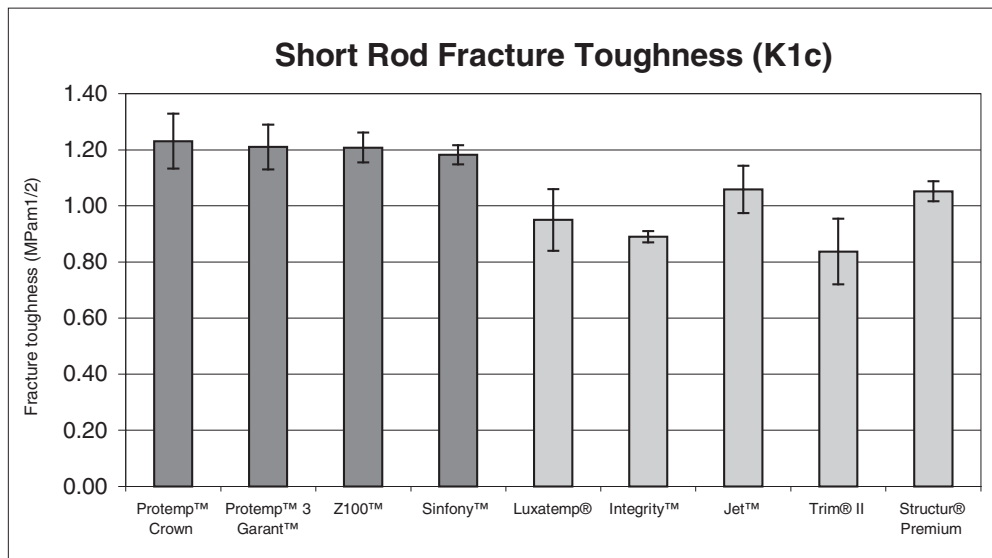


Figure 8. Short Rod Fracture Toughness

Radiopacity

The radiopacity of a temporary material is important for verification of fit and space maintenance of the temporary restoration.

The radiopacity of Protemp Crown was measured according to ISO 4049; the results are shown in the chart below (See Figure 9). Protemp Crown is radiopaque and has greater radiopacity than the other materials tested.

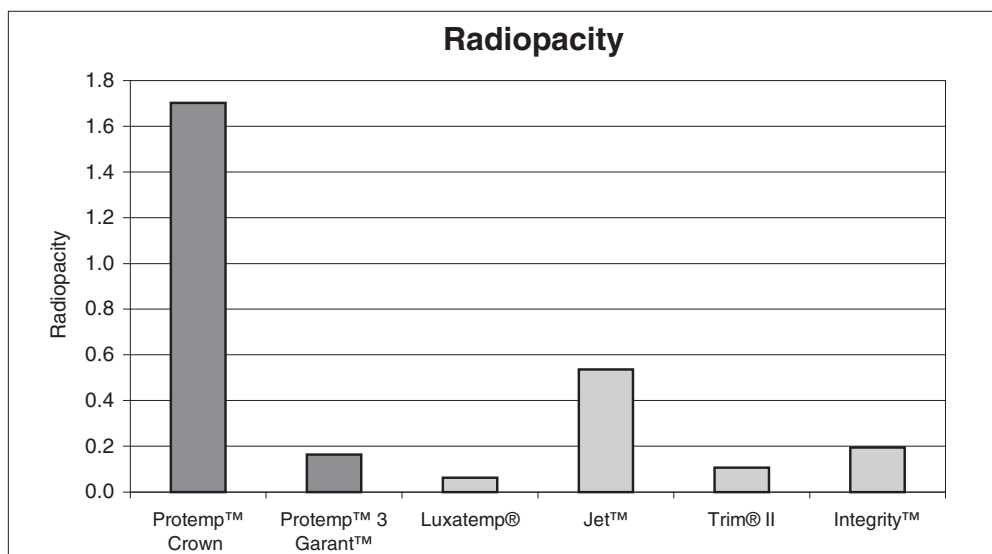
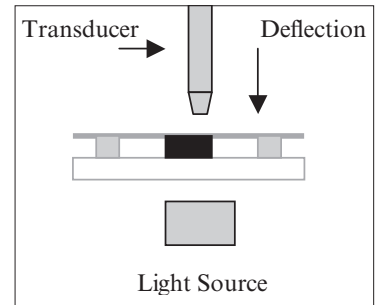


Figure 9. Radiopacity

Polymerization Shrinkage

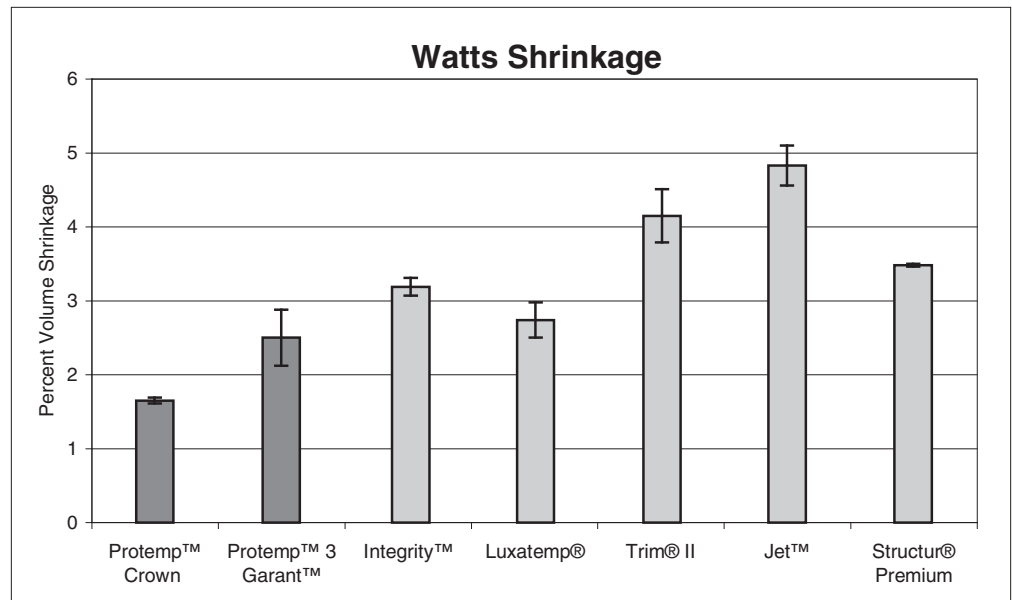
The measurement of shrinkage during polymerization is important for assessing a material's accuracy of fit. Materials with low polymerization shrinkage provide for good clinical fit of the temporary restoration. One standard method for measuring polymerization shrinkage is the method described by Watts and Cash (Meas. Sci. Technol. 1991, 2: 788-794).

In this method, an uncured disc shaped specimen is sandwiched between a glass microscope slide cover and glass plate, then light cured through the lower rigid plate. The flexible microscope slide is deflected during the polymerization of the test specimen. The less the microscope slide bends, the lower the shrinkage. Deflection is measured and recorded as a function of time. Although this process actually measures linear shrinkage, volumetric shrinkage is closely approximated due to the fact that the dimensional changes are mostly limited to the thickness dimension. The lower the value, the less shrinkage.



As the chart below shows, the value of Protemp Crown shrinkage is lower than the other materials tested. (See Figure 10)

Figure 10. Watts Shrinkage



Oxygen Inhibited layer

Protemp Crown offers a material chemistry that leads to a very thin oxygen inhibited layer.

The very low oxygen inhibited layer of Protemp Crown offers minimal resin stickiness on the temporary crown surface that makes handling and shaping much easier. In addition, the low oxygen inhibition allows for simple and fast finishing and polishing. The oxygen inhibited layer of Protemp Crown is significantly less than traditional temporization products (See Figure 11).

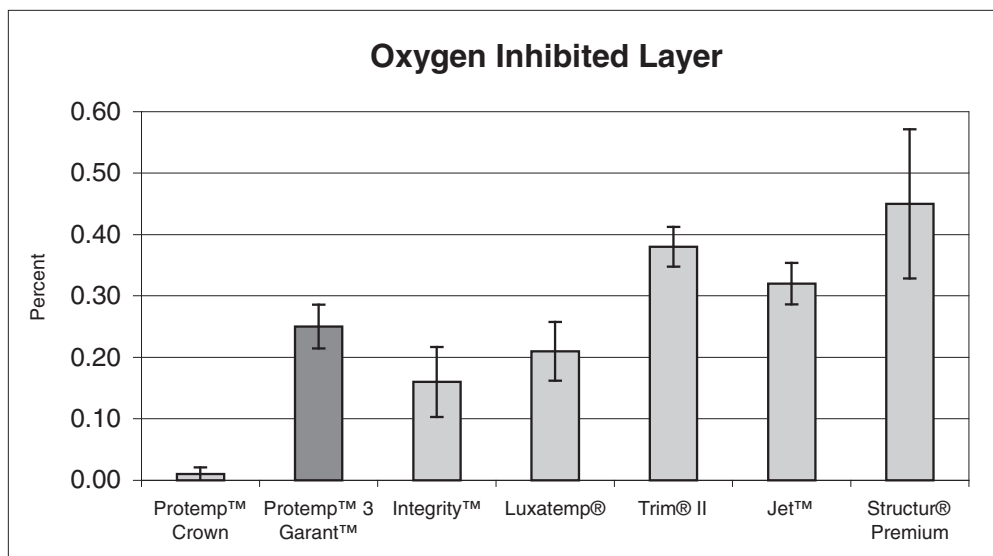


Figure 11. Oxygen Inhibited Layer

Polymerization Temperature Rise

The ability to cure-on-demand is a feature of Protemp Crown that allows dental professionals flexibility during the procedure. In the application of Protemp Crown, the operator has complete control of the set by adapting the crown to the preparation and initiating a tack cure when it is advantageous to do so to hold the material in place. Protemp Crown is intra-orally tack cured using a dental curing light for 2-3 seconds on each of the buccal, lingual and occlusal surfaces. The intra-oral temperature is minimized as the temperature rise is due to the short tack curing rather than a longer time for the chemical reaction. The final light cure (60 seconds) is completed outside of the mouth.

Intra-oral heat during cure was simulated by measuring the effect of light cure on a cylindrical cell of material for 10 seconds. The temperature is measured until it peaks. The maximum temperature reached is divided by the weight of the sample.

Protemp Crown was statistically similar to Protemp™ 3 Garant™ and Structur® Premium, lower than Jet™ and Trim® II and slightly higher than Integrity™ and Luxatemp® (See Figure 12).

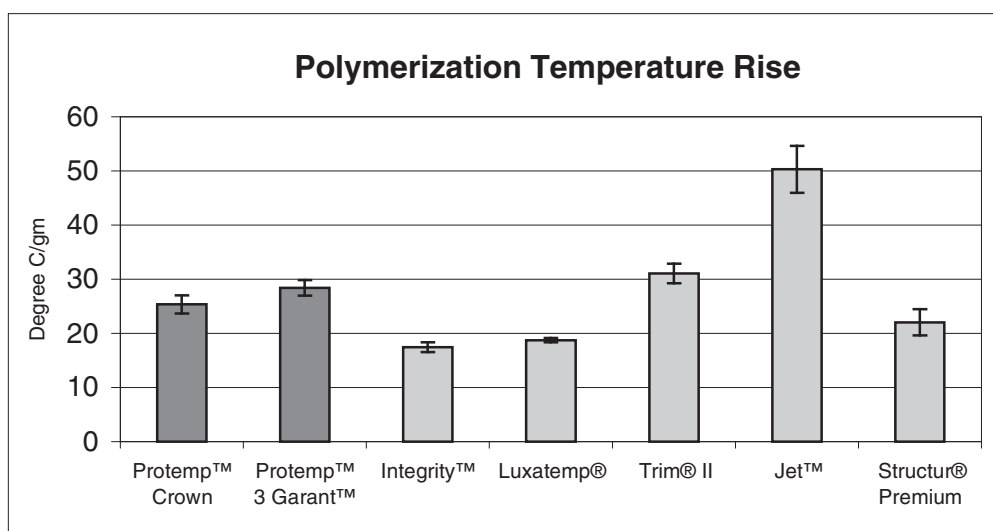


Figure 12. Polymerization Temperature Rise

Material Durability in Mastication Simulator

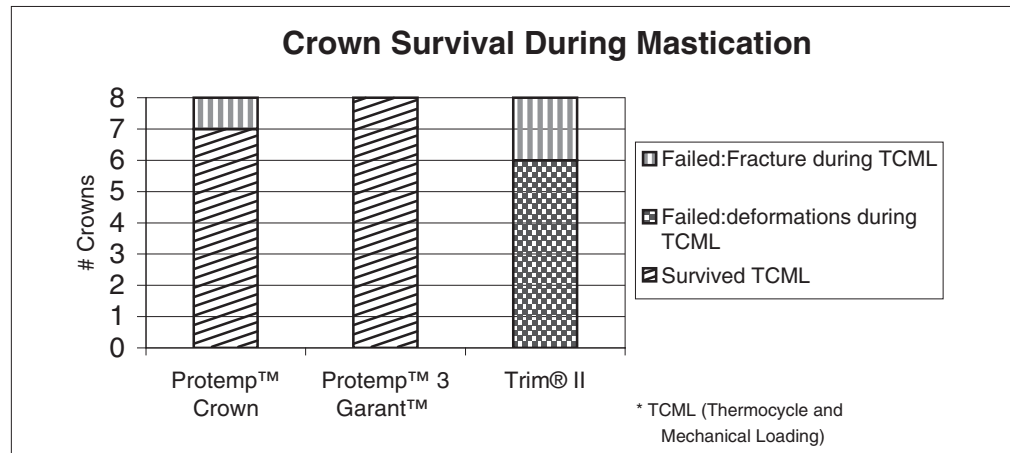
Rosentruitt M, Lang R, University of Regensburg, Germany
IADR abstract NO. 1561 2006

A widely used dynamic in-vitro method for measuring a material's performance regarding wear, marginal fit, fracture strength and simulated chewing force is conducted using a mastication simulator. In this study, at the University of Regensburg, a mastication simulator is used to gain long-term experience through modes of temperature changes (thermocycling) and mechanical loading. The strength of a material and intra-oral influences (fluid, temperature and chewing forces) are simulated to replicate the oral environment. These results are the first indicator for a materials strength and performance over time before it is placed clinically.

In this study for each material combination, 8 identical single-unit temporary crowns were used, and cemented to human molar preparations. Crowns were subjected to thermocycling in water of 5° and 55° C and mechanical loading (50N/1.6Hz/480,000 cycles). A steel sphere was used as the antagonist. The conditions chosen simulated approximately 2 years in the mouth. In addition, overall wear was assessed through SEM examination.

As shown in Figure 13, one Protemp Crown fractured during the thermocycling and mechanical loading test with the remainder surviving. All of the Trim® II crowns failed, six by deformation and two by fracture; all of the Protemp™ 3 Garant™ crowns survived (See Figure 13).

Figure 13. Crown Survival During Mastication Simulation Test



In addition, overall wear was assessed through SEM. Upon examination, Protemp Crown showed a minimal amount of wear demonstrated in the SEM pictures below (figure 14 and 15).

Figure 14 and 15. SEM Pictures: occlusal surface before/after mastication simulator test.

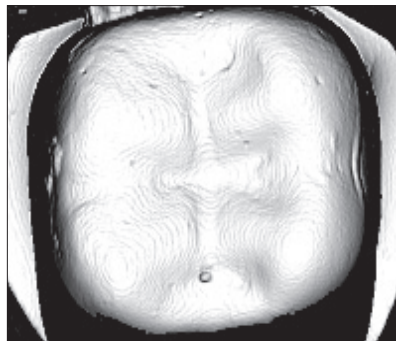


Figure 14) Protemp Crown (before)

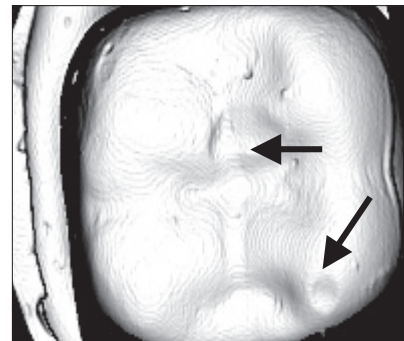


Figure 15) Protemp Crown Wear (after)

This dynamic in-vitro testing completed in the mastication simulator indicates that Protemp Crown Temporization Material is suitable as a temporary restoration.

Global Application Test

In a global application test conducted by 3M ESPE, 105 dentist evaluators placed approximately 1558 temporary single-unit crowns using Protemp Crown Temporization Material from 3M ESPE. The dentist evaluators were selected to represent segments that preferentially use one of the following materials for their single-unit temporary restorations (Prefabricated Crown, Bis-Acrylic, Powder/Liquid). The evaluators completed a questionnaire to report their use and experiences with the Protemp Crown and effectiveness of the final restoration. Also, evaluators compared Protemp Crown to the technique they use most often for single unit temporary restorations.

Placements

Shown below is the total number of Protemp Crowns (temporary single-units) placed during the application test. Dentist evaluators used Protemp Crown for the temporary restoration in the following teeth; molars accounted for 53%, bicuspid (premolar) 30% and cuspids (canine) 17% of all placements. (See Figure 16).

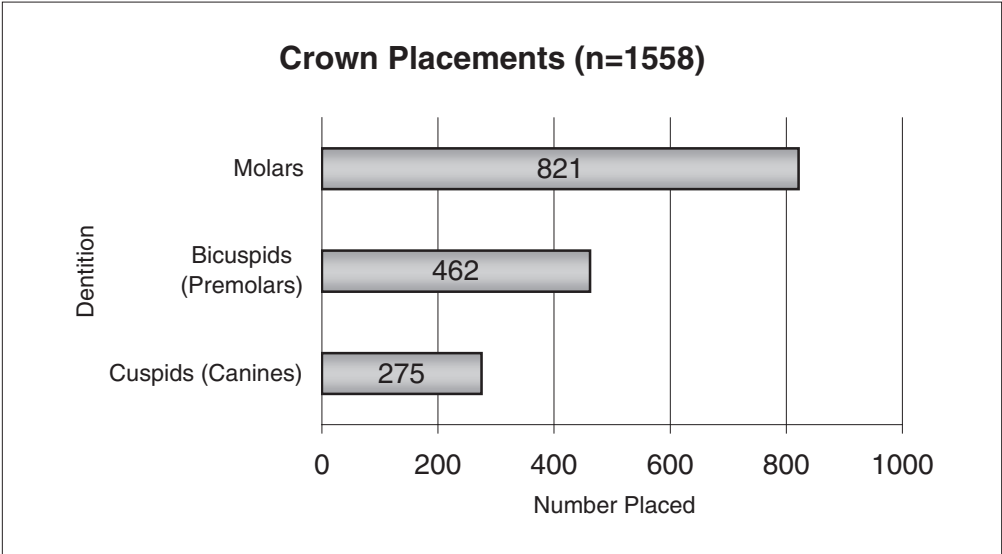
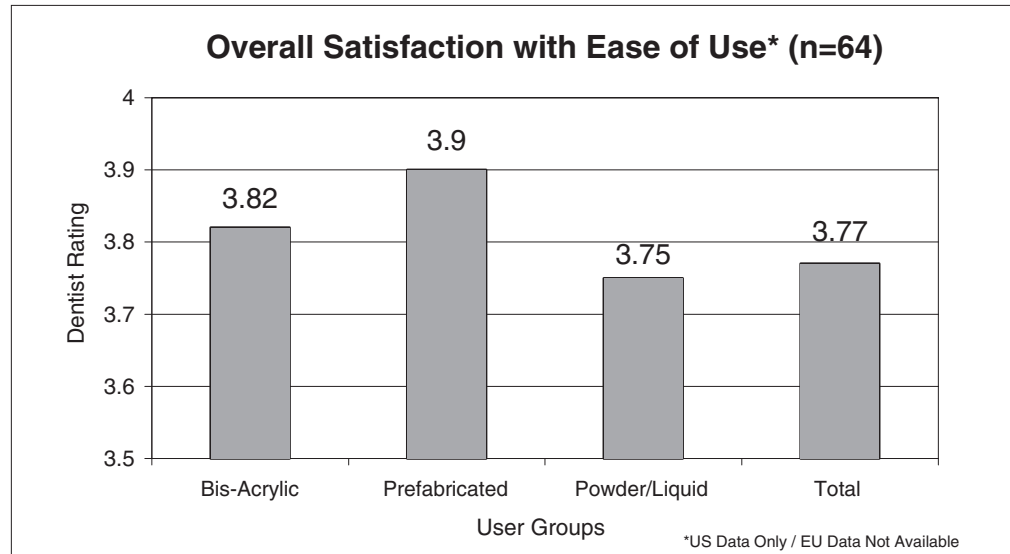


Figure 16. Global Application Test Crown Placements

Ease of Use

The overall satisfaction with ease of use was reported for Protemp Crown and recorded by the dentist evaluators based on the product used most often for single unit temporization. The 64 US dentist evaluators rated the overall satisfaction and ease of use on a scale between Very Difficult (1) and Very Easy (5). As seen in Figure 17, evaluators from the various temporization user groups rated the overall satisfaction with ease of use for Protemp Crown high and therefore easy to use. (See Figure 17).

Figure 17. Overall Satisfaction with Ease of Use

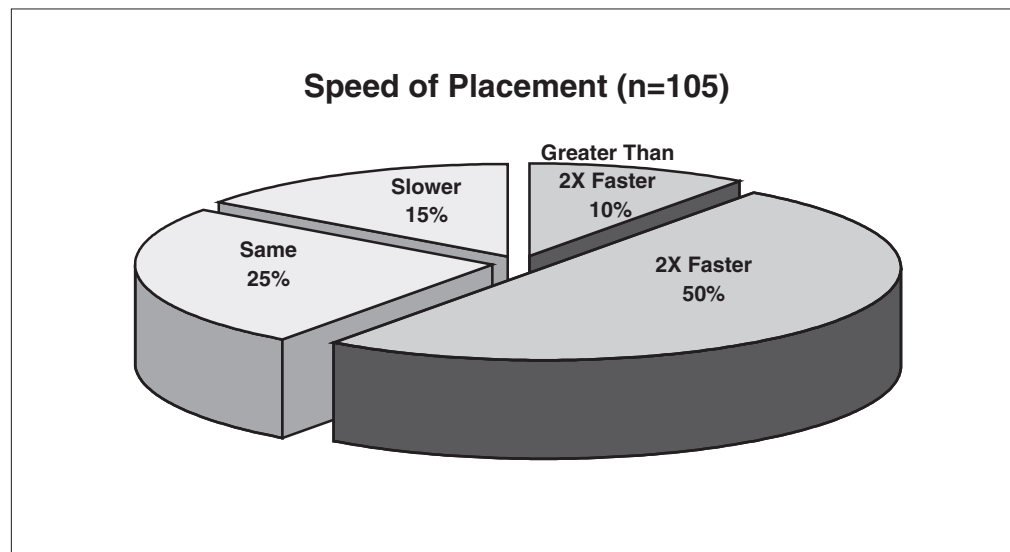


In addition, the evaluators were asked to rate the top 4 reasons why Protemp Crown was easier to use. Dentists responded 1) no impression or matrix needed, 2) no mess or clean-up (i.e.: hardware, mix tips), 3) easy to obtain occlusal fit, and 4) easy to obtain interproximal contacts.

Fast

The speed of placement was rated at least twice as fast by 60% of dentist evaluators when compared to the product used most often for single unit temporary restorations. (See Figure 18)

Figure 18. Speed of Placement



Permanent Crown Fit

The fit of the permanent crown is one indication of the effectiveness of a temporary material and its ability to maintain space and to protect the preparation. During the application test, dentists rated on a scale of Very Poor (1) to Excellent (5), the permanent crown fit after using Protemp Crown as the temporary restoration. The permanent crown fit following a Protemp Crown temporary was rated very good to excellent by the evaluators as shown in Figure 19. (See Figure 19).

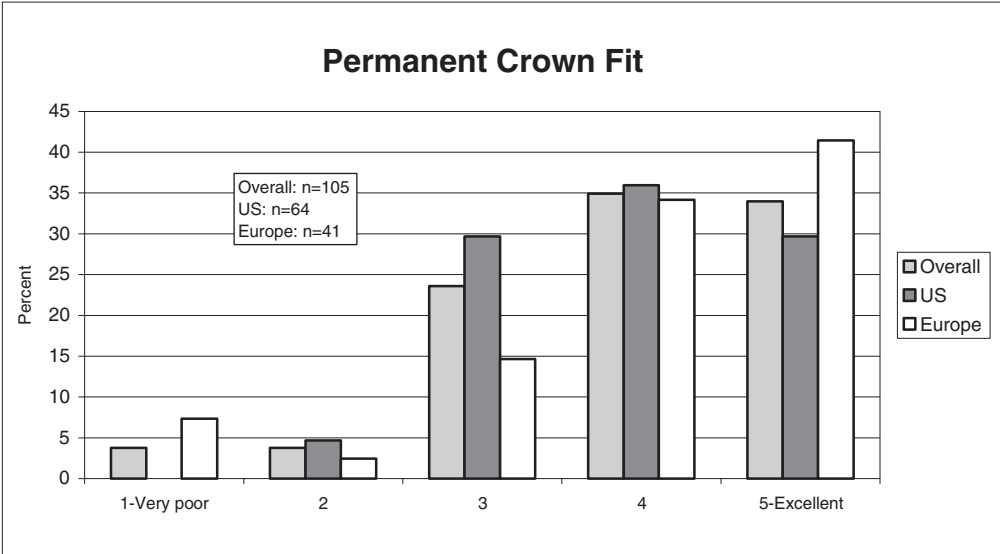


Figure 19. Permanent Crown Fit

Esthetics

The esthetics of Protemp Crown was rated by the dentist evaluators on a scale of Very Poor (1) to Excellent (5). Below is the esthetic rating for Protemp Crown. Esthetics was rated good to excellent by 84% of the dentist evaluators. (See Figure 20)

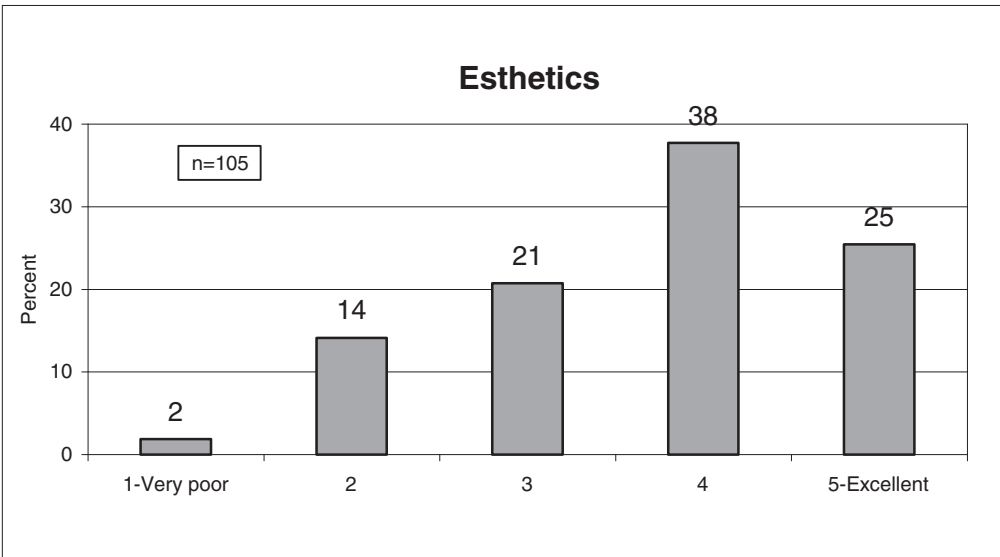
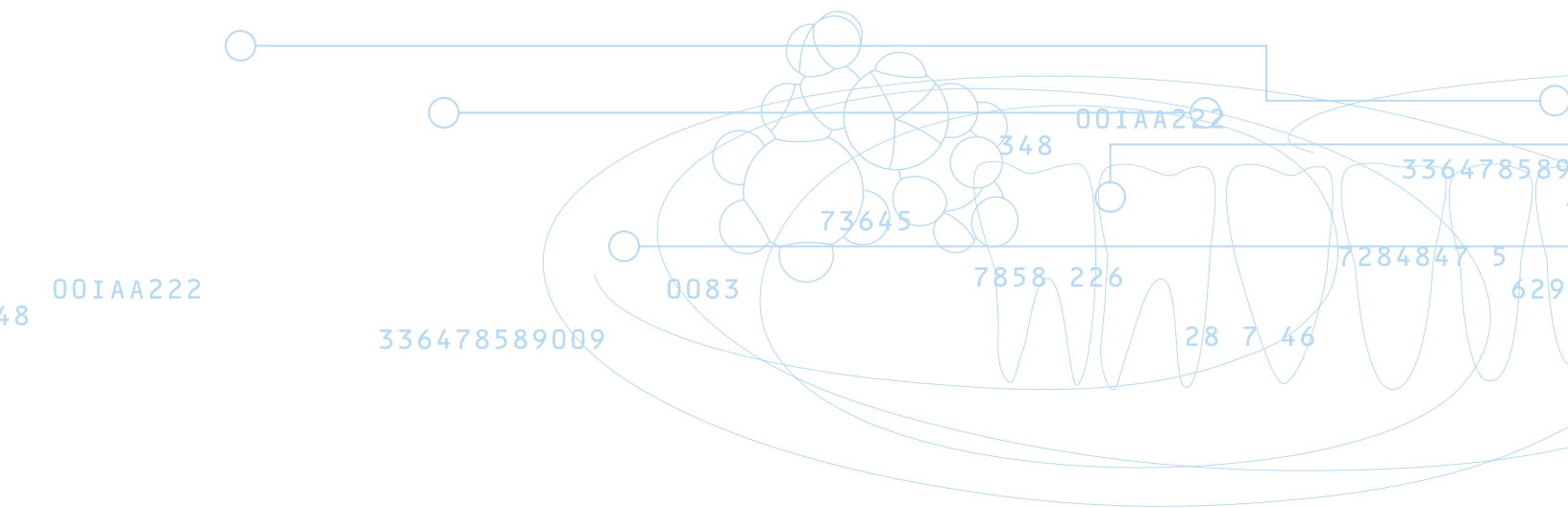


Figure 20. Esthetics

The global application test described in the previous section indicates Protemp Crown Temporization Material from 3M ESPE has excellent clinical performance and proven acceptance when used for single-unit temporary applications in permanent dentition.

This innovative development allows Protemp Crown to be considered the next generation temporary single-unit crown material. The clinical aspects and material properties ensure that the daily application in the dental operatory is easy to use, fast, and provides for excellent strength and esthetics.



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